UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY CIVIL ACTION NO 16-MD-2738 (FLW) (LHG)

IN RE JOHNSON & JOHNSON : DAUBERT HEARING POWDER PRODUCTS MARKETING, : JULY 22, 2019 SALES PRACTICES.

: VOLUME 1

CLARKSON S. FISHER UNITED STATES COURTHOUSE 402 EAST STATE STREET, TRENTON, NJ 08608

B E F O R E: THE HONORABLE FREDA L. WOLFSON,

APPEARANCES:

BEASLEY ALLEN, ESQUIRES

BY: P. LEIGH O'DELL, ESQUIRE (ALABAMA) MARGARET M. THOMPSON, ESQUIRE (ALABAMA) -and-

ASHCRAFT & GEREL, ESQUIRES

BY: MICHELLE A. PARFITT, ESQUIRE (VIRGINIA)

-and-

MOTLEY RICE, ESQUIRES

BY: DANIEL R. LAPINSKI, ESQUIRE (NEW JERSEY) On Behalf of the Plaintiffs Steering Committee

DRINKER, BIDDLE & REATH, ESQUIRES

BY: SUSAN M. SHARKO, ESQUIRE (NEW JERSEY) JULIE L. TERSIGNI, ESQUIRE (NEW JERSEY)

-and-

SKADDEN, ARPS, SLATE, MEAGHER & FLOM, ESQUIRES JOHN H. BEISNER, ESQUIRE (WASHINGTON, D.C.)

-and-

PROSKAUER ROSE, ESQUIRES

BY: BART H. WILLIAMS, ESQUIRE (CALIFORNIA) OM ALLADI, ESQUIRE

(Continued.)

VINCENT RUSSONIELLO, RPR, CRR, CCR OFFICIAL U.S. COURT REPORTER (609) 588-9516

2 APPEARANCES CONTINUED: WEIL, ESQUIRES By: ALLISON M. BROWN, ESQUIRE On behalf of Defendant Johnson & Johnson SEYFARTH SHAW, ESQUIRES BY: THOMAS L. LOCKE, ESQUIRE (WASHINGTON D.C.) On Behalf of Defendant Personal Care Products Council

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3
                 MORNING SESSION
1
 2
            (In open court.)
 3
            THE DEPUTY CLERK: All rise.
 4
 5
            THE COURT: Thank you. I do have the sign-in
 6
    sheet. If I could just have the appearances at
7
    counsel table, who will be participating in the
8
    hearing for plaintiffs, please.
            MR. LAPINSKI: Your Honor, good morning.
 9
            Good morning, your Honor.
10
            Daniel Lapinski, Motley Rice, on behalf of
11
12
    plaintiffs.
13
            MS. O'DELL: Good morning, your Honor.
            Leigh O'Dell on behalf of the plaintiffs
14
15
    Steering Committee.
16
            MS. THOMPSON: Good morning, your Honor.
17
            Margaret Thompson, Beasley Allen.
            MS. PARFITT: Good morning, your Honor.
18
    Michelle Parfitt, Ashcraft & Gerel.
19
20
            MR. WILLIAMS: Good morning, your Honor.
21
            Bart Williams on behalf of defendant Johnson &
    Johnson.
2.2
23
            MR. ALLADI: Good morning, your Honor.
            Om Alladi on behalf of defendant Johnson &
24
25
    Johnson.
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4
            MS. BROWN: Good morning, your Honor.
1
 2
            Allison Brown, Weil, Gotshal for Johnson &
 3
    Johnson.
            MS. SHARKO: Susan Sharko, Drinker Biddle, for
 4
    Johnson & Johnson defendants.
 5
            MS. TERSIGNI: Julie Tersigni, Drinker
 6
7
    biddle, for the Johnson & Johnson defendants.
8
            MR. BEISNER: Good morning, your Honor.
 9
            John Beisner, Skadden, Arps, for the Johnson &
    Johnson defendants.
10
11
            MR. LOCKE: Good morning, your Honor.
12
            Thomas Locke, Seyfarrth & Shaw, for Personal
    Care Products Council.
13
            (Brief recess is taken.)
14
15
            MR. LAPINSKI: Our first witness, we would
    like to call Dr. Ghassan Saed.
16
17
    GHASSAN SAED, called as a witness on behalf of the
18
    plaintiffs, having been first duly sworn, testified as
19
20
    follows:
21
    DIRECT EXAMINATION
2.2
    BY MR. LAPINSKI:
23
24
    Q. Dr. Saed, good morning. We are here today as
25
    part of the Daubert hearing. This is not a trial.
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When did you make those corrections, Dr. Saed? Q.

The date of my second deposition. Α.

24

recruited to Wayne State University in 1998, and this

diseases. I have shown in the past 25 years of my

1 experience this balance is altered in ovarian cancer.

2 Also other people have shown a different type of

3 cancer. Balance between oxidants and antioxidant is

4 called the "redox balance."

5

6

7

8

9

Your Honor, this is like you have hormones
that increase blood sugar, hormones that decrease
blood sugar. The balance between the two is what
maintains blood sugar within normal just as an example
to simplify it.

- 10 Q. Dr. Saed, would you describe for the Court your
 11 professional experience as it relates to oxidative
 12 stress and ovarian cancer?
- 13 A. I have published over 140 peer-reviewed articles
 14 in different specialty journals. Over 50 of these
 15 articles are specifically related to oxidative stress
 16 and ovarian cancer.
- 17 Q. Have you done specific research in this area as well?
- A. Yes. My lab is focussed on studying oxidative stress, inflammatory markers in the pathogenesis in the causation of ovarian cancer.
- 22 Q. Has any of your work been published in books?
- 23 A. Yes. I was just -- I just published a book. I
- 24 was invited to participate in a book chapter in this
- 25 book. The book is called "The Pathogenesis of Ovarian

Cancer From Pathogenesis to Treatment," and I 1

2 participated in a chapter. The chapter title is "New

3 Insights Into the Pathogenesis of Ovarian Cancer in

- Relation to Oxidative Stress." 4
- Doctor, have you published review articles in 5
- the area of oxidative stress and ovarian cancer? 6
- 7 Yes. I just published a review article that Α.
- 8 just came out in the GYN Oncology, which is a
- prestigious journal for our research. And also I have 9
- other review articles in the same area. 10
- Q. Doctor, is there more significance to the 11
- 12 publication of a review article as compared to a
- 13 simple publication in a journal?
- Yes. Usually, the review articles are written 14
- 15 by experts in the field, where regular manuscripts are
- 16 written by scientists or anyone.
- 17 0. How many different times have you written a
- review article on the topic of "oxidative stress"? 18
- Maybe around nine or ten. 19 Α.
- Have you ever lectured on the topic of oxidative 20
- stress in ovarian cancer? 21
- 2.2 Α. Yes. Many times. I was an invited speaker at
- 23 the grand rounds at the national level, lectures in
- 24 the hospitals, and at the national level, also
- international level. 25

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10
          Have you ever done work on behalf of medical
1
 2
    journals?
          Yes. I act as a reviewer to several journals
 3
    including GYN Oncology, Reproductive Sciences,
 4
 5
    American Society For Reproductive Medicine, and many
 6
    others.
 7
            MR. LAPINSKI: Your Honor, do you have any
8
    questions with respect to the Doctor's qualifications.
 9
            THE COURT: I do not.
10
11
    BY MR. LAPINSKI:
12
13
          Doctor, you had mentioned you had recently
    published in Gynecologic Oncology a review article.
14
15
    Is this the review article you were referring to that
    is on the screen?
16
17
    Α.
          Yes.
          Doctor, is this the review article that you were
18
    referring to that was published in Gynecologic
19
    Oncology?
20
21
    Α.
          Yes.
2.2
    Q.
          What's the title?
          It's "Updates of the Role of Oxidative Stress in
23
    Α.
24
    the Pathogenesis of Ovarian Cancer."
            MR. LAPINSKI: Your Honor, for your reference
25
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- 1 | a copy of this article is in the binder, and it was
- 2 | previously marked as PSC GC OPP, Exhibit 113.
- 3 BY MR. LAPINSKI:
- 4 Q. Dr. Saed, in the title of the article, what does
- 5 | "pathogenesis" mean?
- 6 A. It means causation of ovarian cancer.
- 7 Q. In lay terms, what is this review article about?
- 8 A. The take-home message from this review article
- 9 is that oxidative stress plays a very important and
- 10 essential role in causation of ovarian cancer.
- 11 | Q. Doctor, in the highlighted section, the first
- 12 | bullet, what's the first bullet in the highlight
- 13 | section of your article?
- 14 | A. It says: "Oxidative stress plays an essential
- 15 role in the pathogenesis of ovarian cancer."
- 16 Q. What's the purpose of the highlight section in
- 17 | journal articles?
- 18 A. Take-home message to readers.
- 19 Q. Doctor, if you could turn to your expert report
- 20 | page if 20. Doctor, what are the six primary opinions
- 21 | that you are offering in this litigation?
- 22 A. I am offering, first of all, that Johnson &
- 23 | Johnson baby powder is not inert. It has a biological
- 24 activity. This biological activity includes causation
- 25 of inflammation. It increases inflammation. It

increases the redox balance, the balance that keeps oxidants antioxidants in balance. It changes the redox balance in normal surface ovarian cells to mimic the profile that we see and we observe in ovarian cancer cell lines.

Also, Johnson & Johnson Baby Powder exposure can elevate CA-125, which is a marker of inflammation, and it is a biomarker for ovarian cancer for monitoring prognosis and treatment. And, also, it induces, which is very important, changes in the DNA by inducing mutations in the DNA, and not any random mutation; these mutations were detected in these key enzymes that regulate the oxidants and antioxidants of the cell.

It is based on all that, it is my opinion, and based on the literature, and based on my 25 years plus experience in this field, it is my opinion that exposure to talcum powder at the cellular level will induce cells to transformation.

- Q. When you say "induce cells to transformation," what do you mean by that?
- A. It means, because we have done assays that are indicative of cells undergoing the transformation process, and these tests are looking at cell proliferation and cell apoptosis; and when we did

- 1 | those two tests we found exposure to normal cells of
- 2 Johnson & Johnson Baby Powder severely increased the
- 3 proliferation of cells which is uncontrolled cell
- 4 division and decreased simultaneously apoptosis, which
- 5 | is the natural cell death process for elimination of
- 6 | bad cells, and that is an indication of cells
- 7 undergoing transformation process.
- 8 Q. Dr. Saed, are you offering an opinion in this
- 9 case that Johnson's Baby Powder causes ovarian cancer?
- 10 A. Yes.
- 11 | Q. Doctor, are you also offering an opinion in this
- 12 | case that exposure to Johnson's Baby Powder worsens
- 13 | the prognosis for women who already have ovarian
- 14 | cancer?
- 15 A. Yes.
- 16 | Q. You touched on it a little bit. But upon what
- 17 | are your opinions that you are offering in this case
- 18 based?
- 19 A. They are based on the 2 years of research that I
- 20 | spent looking at the effect of exposure of Johnson &
- 21 | Johnson Baby Powder to normal ovarian cells and
- 22 | compared that effect to what we know, what others know
- 23 about the effect on ovarian cancer cancer cells. So
- 24 we compared the two.
- 25 And also in other published literature out

14 there. 1 2 Q. Doctor, do you need to conduct additional 3 research to support the opinions that you are offering in this case? 4 5 Α. No. Why is that? 6 Q. 7 In vitro studies, which I did, they are the gold 8 standard for trying to figure out the mechanism of the 9 effect of any agent, exposure to any agent in cell culture. 10 Q. Would you explain to the Court what an in vitro 11 12 study is? In vitro study it is using cell culture petri 13 dishes outside the body in the lab. 14 You've referenced the term "biologic activity." 15 Would you explain what you mean by "biologic 16 17 activity." Biological activity is induction by exposure to 18 Johnson & Johnson Baby Powder includes all what I've 19 just listed. It induces inflammation; it induces 20 21 proliferation; it inhibits cell death; changes the redox balance of the cell that mimics what we see in 2.2 23 ovarian cancer cells that we studied for 25 plus 24 years.

MR. LAPINSKI: Your Honor, if I can approach

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15
    the witness in order to be able to hand him an
1
 2
    exhibit.
 3
            THE COURT: Yes.
 4
    BY MR. LAPINSKI:
 5
    Q. Dr. Saed, I've just handed you two books. Would
 6
    you describe for the Court what those books are.
 7
8
    Α.
         Those are lab notebooks.
 9
         Are they the laboratory notebooks that contain
    your information related to the research you have done
10
    on talcum powder?
11
12
    A. Yes.
13
            MR. LAPINSKI: Your Honor, those notebooks
14
    were previously marked at his initial deposition as
    Exhibits 2 and 3.
15
            THE COURT: Okay.
16
    BY MR. LAPINSKI:
17
          Dr. Saed, if you would please go to the binder
18
    that we have. If you would look, Dr. Saed, at Exhibit
19
20
    PSC SAED OPP Exhibit I.
21
    A.
         I'm here.
2.2
            (Pause.)
23
          Dr. Saed, what is the document that you are
24
    currently looking at?
          This is the first section of the lab notebook.
25
    Α.
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This is the very initial study that we conducted using talcum powder from Fisher Scientific.

THE WITNESS: Your Honor, here we used Fisher Scientific talcum powder, and we used this powder to treat three different cancer cell lines -- ovarian cancer cell lines, one normal macrophage, and one normal ovarian epithelial cell line.

- Q. What type of test did you run related to this section of your laboratory notebooks, Doctor?
- A. Here we did different doses of the talcum powder. We used 20, 100, and a thousand microgram per milliliter, and then we measured different markers of oxidative stress. We measure -- in the table we have a list of all the markers that we tested in this study.

Now, the outcome of the study, your Honor, is published in an abstract that we submitted to the Society For Reproductive Investigation, and it was presented in their meeting March of 2018.

MR. LAPINSKI: Your Honor, the March 2018 abstract that was presented at the Society For Reproductive Investigation is in your binder as PSC SAED OPP Exhibit J.

THE COURT: This isn't one of the journals you identified as serving as a review on, is it?

17 THE WITNESS: Yes. 1 2 3 BY MR. LAPINSKI: Dr. Saed, if you would turn to the next section 4 of the binder which is PSC SAED OPP Exhibit G. 5 6 Α. Yes. 7 If you could please describe for the Court what 8 that document is. Here we tried different time points. We used 9 24 hours, 48 hours, 72 hours, with higher doses of the 10 powder. And then we looked at CA-125 levels, which is 11 12 the inflammatory level biomarkers for ovarian cancer, 13 and we found that exposure of normal cells to talc induces CA-125 levels, and we published this -- we 14 presented this in an abstract in March 2018 in the SRI 15 meeting, the Society for Reproductive Investigation 16 17 meeting. What is the significance of an increase in the 18 CA-125 levels? 19 It is very significant because it is a marker of 20 inflammation, and it is a cancer antigen marker. And 21 2.2 if it's increased upon exposure with talcum powder, it is an indication the cells are going into 23 24 inflammation. 25 MR. LAPINSKI: Your Honor, for your reference,

- 1 | the abstract that was presented at the SRI meeting
- 2 related to CA 125 is in the back of your binder, and
- 3 that has been marked as PSC SAED OPP Exhibit L.
- 4 Q. Dr. Saed, in your binder, if you would take a
- 5 look at PSC SAED OPP Exhibit H.
- 6 A. Yes.
- 7 Q. What is that document, Doctor?
- 8 A. Here, your Honor, we did only Johnson & Johnson
- 9 Baby Powder, and here we looked at three cancer cell
- 10 | lines: ovarian cancer cancer cell lines and three
- 11 | normal ovarian epithelial cell lines, and we looked at
- 12 doses that was zero, five, 20 and 100, microgram per
- 13 milliliter. And then we exposed cells to 72 hours,
- 14 | and we looked at different markers of oxidative
- 15 stress, inflammation, apoptosis, proliferation, cell
- 16 division, and genetic mutations.
- 17 Q. Doctor, were the results of this research
- 18 | published?
- 19 A. Yes.
- 20 | Q. Where and when were they published?
- 21 A. It is published now in a manuscript for Society
- 22 | For Reproductive Sciences. It is in the Reproductive
- 23 | Sciences Journal.
- 24 THE COURT: Let me ask one question with
- 25 | regard to the lab notebooks.

1 | touched the data. Methodology part is what's

2 handwritten or sometimes stuck as a procedure in the

3 lab notebook.

4 Q. Dr. Saed, you referenced the handwriting in the

5 methodology parts of the lab notebooks. The methods

6 | that you employed during the work and the experiments

7 | you did related to these lab notebooks, are those

8 | methods, methods that you employed in the past?

9 A. Yes. These are established methods in our

10 | laboratory and also very well known to the scientific

11 research community. They have been out for several

12 decades now. We use them for clinical testing.

For example, ELISA is a very established

14 | clinical technique that doctors ask. For example,

15 | CA-125. It is clinically standardized not just for

16 research purposes. These are very well known

17 established methods. It has been there for decades.

18 Q. Doctor, you touched on it a little bit, but in

19 regard to the data that was compiled for purposes of

20 | your research, could you please explain that data

21 process?

2.2

A. Yes.

23 As I said, our machines now are computerized.

24 | So you perform the assay using the machine. The

25 | machine gets the data in the computer. We export the

- 1 data from the computer. The data is transformed into
- 2 | a spreadsheet that has all the formulas, because we
- 3 | have done this several times, and the spreadsheet will
- 4 | calculate -- because it has all the formulas, it will
- 5 | compute all the numbers.
- 6 What we do, just to confirm, we print them out
- 7 from the computer and stick them in that notebook.
- 8 Q. Doctor, is there any data from your talcum
- 9 powder experiments that has been manually entered into
- 10 | the laboratory notebooks?
- 11 A. No.
- 12 Q. I would like to be able to take a look at page
- 13 | 49 of the laboratory notebook.
- MR. LAPINSKI: Your Honor, the laboratory
- 15 notebooks have handwritten numbers at the bottom of
- 16 | the pages. You can use that for your reference.
- 17 | Q. Doctor, you see the image of page 49 up on the
- 18 | screen. What does the data on this page represent?
- 19 A. Here we measured GPX, which is known
- 20 | antioxidant, and we measured it in cells -- three
- 21 | normal, and three ovarian cancer cells exposed to
- 22 | various doses -- 5, 20 and 100 micrograms per ml of
- 23 Johnson & Johnson Baby Powder for 72 hours.
- 24 Q. Doctor, during your prior depositions questions
- 25 | you were asked about the data in this spreadsheet and

- specifically the second average listed in the spreadsheet that has a value of 2.47.
- 3 MR. LAPINSKI: Your Honor, it is in the upper 4 right-hand side corner.
- 5 Q. Doctor, is the 2.47 calculation correct?
- 6 A. Yes, yes.
- 7 Q. Could you explain why it is correct?
- 8 A. Because it is taking the average of the three 9 values that are in the column where it says PG, 10 picogram.
- THE COURT: This is on page 49?
- 12 THE WITNESS: Yes.
- MR. LAPINSKI: Cory, could you go back to the full screen shot. It is in the upper right-hand corner. It is not highlighted in the lab notebook.
- 16 We're highlighting it for purposes here.
- Q. Doctor, I want to take a step back now that Judge Wolfson has page 49 in front of her.
- During your deposition you were asked
 questions about the values in the spreadsheet, and you
 were specifically asked a question about the 2.47
- 22 average that's in the upper right-hand corner of the
- 23 | spreadsheet. Is that calculation correct?
- 24 A. Yes.
- 25 | Q. Would you please explain to the Court why that

1 | calculation is correct?

2

3

4

17

- A. Your Honor, this is the average of the three numbers highlighted in the column under picogram excluding the outlier. It is the average of 2.5 and
- 5 2.44, excluding 2.21 as an outlier.

We have formulas in all of these columns, and
the average -- all the averages are not the normalized
value. The averages is for the column that is
picogram per microliter RNA.

- 10 Q. Doctor, you used the term "outlier." What is an outlier?
- 12 A. An outlier is statistically a different number 13 than the other two. That's what an outlier is.
- Q. Dr. Saed, at the time of your depositions you were unable to testify as to the accuracy of that calculation. For what reason were you unable to
- 18 A. Your Honor, we have over 5,000 data points in
 19 the calculation, over a dozen formulas; and when I was
- 20 asked during my deposition, I could not recall. When
- I went to the lab, I checked the formulas and everything is correct.

testify as to the accuracy?

- Q. Doctor, the formulas that are in this
 spreadsheet, are those formulas calculated manually?
- 25 A. No.

2.4

- 1 Q. How are they calculated?
- 2 A. Electronically.
- 3 Q. If we could go to page 61 of the laboratory
- 4 notebook.
- 5 Doctor, what does the data on page 61 of the
- 6 | laboratory notebook represent?
- 7 A. This data here represents ELISA assay measuring
- 8 | catalase activity in cells treated with Johnson &
- 9 Johnson Baby Powder for increasing dosage for
- 10 | 72 hours.
- 11 Q. Doctor, during your deposition you were asked
- 12 questions about the data in this spreadsheet as well,
- 13 and specifically you were asked about the 11.07 value
- 14 | in the upper right-hand side corner of this
- 15 spreadsheet. Is the 11.07 calculation correct?
- 16 A. Yes.
- 17 Q. Could you please explain why that calculation is
- 18 | correct?
- 19 A. It is the same way. It is the average of the
- 20 | three numbers -- 9.98, 11.63, 10.50, eliminating the
- 21 outlier, which is, in this case, 9.98. I don't
- 22 | eliminate the outliers manually. The outliers are
- 23 eliminated by a formula set up in the computer.
- 24 THE COURT: Why would that be an outlier as
- 25 opposed to the 11.63? How did you make that

```
2.5
    determination? Because that's also more than one from
1
 2
    the 10.50. How did you make that determination?
 3
            MR. LAPINSKI: Cory, do you have the ability
    to bring up the full page?
 4
 5
          Your Honor, this is based on several formulas in
    the vertical column not just one factor. There are a
 6
 7
    lot of corrections to get into that average, and this
8
    is set electronically by the formula.
          Doctor, in response to Judge Wolfson's question,
 9
    you referred to the fact that the 9.98 -- strike that.
10
            Doctor, could you explain again to the Court
11
12
    why the 9.98 would not just by default -- I'm sorry --
13
    why the number other than the 9.98 would be the
    outlier?
14
15
         Your Honor, as I said, these formulas are all
16
    electronically computed, and they are put in based on
17
    a certain calculation. If you look at the vertical
    column, you will see all these are corrections for
18
    certain blanks and standards to compute that formula.
19
    This is what the formula ended up doing.
20
21
         Doctor, when you used the word "correction," can
    Q.
22
    you explain to the Court what you mean by the word
```

24 Correction controlling for the blank, 25 controlling, for the changing in the assay.

"correction"?

you were unable to testify as to the accuracy of the

- 1 numbers. What was the reason for that?
- 2 A. Your Honor, the same reason; there are too many
- 3 data points. There are over 5,000 data points, a lot
- 4 of formulas. I cannot recall the exact formula at
- 5 | this time when they asked me about it.
- 6 THE COURT: By looking at these documents, the
- 7 | spreadsheet, can you tell what the formula is that was
- 8 used?

- 9 THE WITNESS: From looking at the spreadsheet
- 10 itself, no. I have to look at the Excel sheet and in
- 11 | the column, it says the formula.
- 13 BY MR. LAPINSKI:
- 14 Q. Doctor, the formulas that you are referring to,
- 15 | where are the formulas derived from?
- 16 A. In this case, this is ELISA, so it comes from
- 17 | the manufacturer, the kits. This is taking into
- 18 account extinction coefficient, the slope of the
- 19 | standard curve. There are many formulas involved
- 20 here.
- 21 MR. LAPINSKI: If we could please go to page
- 22 | 104 of the laboratory notebook.
- 23 Your Honor, we're actually going to be looking
- 24 at page 103 and 104.
- 25 Q. Doctor, what does the data on page 104 of the

- 1 | laboratory notebook represent?
- 2 A. It represents a single nucleotide polymorphism
- 3 | in different markers that we studied. In this
- 4 | specific one, it looks like catalase, which is a
- 5 powerful antioxidant enzyme.
- 6 Q. One of the defendants' experts, Dr. Boyd, has
- 7 | stated that for the two rows of the Excel spreadsheet
- 8 | that are marked TOV 112-T alleles 1 and 2 should equal
- 9 1.0.
- 10 What is your opinion on that?
- 11 A. If you look at the upper -- here this is the
- 12 | frequency -- they add up --
- 13 | Q. I'm going to interrupt you for a second.
- 14 Doctor, you are referring to the catalase, and
- 15 | that's on page 103 of your lab notebook. Correct?
- 16 A. Correct.
- 17 O. Continue.
- 18 A. They add up to 100 percent, 1.0.
- 19 MR. LAPINSKI: Your Honor, for your reference,
- 20 that's the upper left-hand corner, the highlighted
- 21 | line that says SNP assay CAT.
- 22 | Q. Those add up to 100 percent?
- 23 A. Yes.
- If you go down to the other sheet, the other
- 25 | sheet here representing CHI square, after running the

- 1 statistical analysis of the data, it is represented
- 2 here.
- 3 Q. Doctor, would you expect the lines in the
- 4 | spreadsheet on page 104 to add up to 1.0?
- 5 A. No.
- 6 Q. Doctor, are you aware of any data from your
- 7 Johnson's Baby Powder research that's incorrect?
- 8 A. No.
- 9 Q. How can you be sure of that?
- 10 A. All our data is electronically calculated; and
- 11 to keep the record in the lab, we print them out from
- 12 | the computer and we stick them in the notebook.
- MR. LAPINSKI: Your Honor, if I can approach
- 14 | the bench, I want to take one of the laboratory
- 15 | notebooks from you.
- 16 THE COURT: One or two?
- MR. LAPINSKI: It's the one that's not labeled
- 18 | "Temple." It says "Nicole" on the binding of it.
- 19 Q. Dr. Saed, the defendants have argued that there
- 20 | have been pages removed from your laboratory
- 21 | notebooks, and, in particular, the defendants have
- 22 | made the argument that approximately 10 pages have
- 23 been removed including pages 52, 74, 108 through 113
- 24 | and 120.
- What I would like to do is put up on the ELMO

- 1 page 52 of your laboratory notebook. Is page 52 of
- 2 your laboratory notebook missing?
- 3 A. No.
- 4 Q. What's reflected on page 52 of your laboratory
- 5 | notebook?
- 6 A. It is a blank page.
- 7 Q. Why would there be blank pages in your
- 8 | laboratory notebook, Doctor?
- 9 A. Because this is the end of the section to start
- 10 a new section.
- 11 | Q. What's the significance of each section in
- 12 general, if you remember referencing a second? Why
- 13 does your notebook have different sections?
- 14 | A. Before we start the experiment, we run different
- 15 experiments at the same time or similar time. We
- 16 predivide before we start the experiment. We divide
- 17 | the lab notebooks into sections and label them.
- 18 If you look at the lab notebook, your Honor,
- 19 you will see these stickers that says ELISA. This is
- 20 | the section where we do ELISA and we write all the
- 21 results in it.
- 22 The next section is statistics. This other
- 23 section is genetic mutations. We do this before we do
- 24 | anything. We just estimate how many pages we need and
- 25 divide the lab notebook into sections; and when the

```
31
    data comes in, we put them in the corresponding
1
 2
    sections.
 3
            THE COURT: Who put the little stickies on
    with those words, like ELISA that I see there?
 4
 5
             THE WITNESS: My research assistant.
             THE COURT: When is that done?
 6
 7
             THE WITNESS: When we started to do the
8
    experiment.
 9
             THE COURT: Right at the outset?
             THE WITNESS: Yes, before we fill in any data.
10
11
12
    BY MR. LAPINSKI:
13
          Dr. Saed, I'm next going to show you page 74 of
14
15
    your laboratory notebook. Is page 74 of your
    laboratory notebook missing?
16
17
    Α.
          No.
          What's on page 74 of your laboratory notebook?
18
    Q.
19
          Same. It is a blank page.
    Α.
20
          Doctor, we're going to look at pages 108 through
    Ο.
    113 of your laboratory notebook. Are pages 108
21
2.2
    through 113 of your laboratory notebook missing?
23
    Α.
          No.
24
          What's on those pages, Doctor?
    Q.
25
          The blank pages.
    Α.
```

- 1 Q. How about page 120, Doctor? You taped in some
- 2 | additional data. Correct?
- 3 A. No. This is already there.
- 4 Q. Is page 120 missing, Doctor?
- 5 | A. No.
- 6 MR. LAPINSKI: Your Honor, if I could approach
- 7 | the bench, I'm going to give you the laboratory
- 8 | notebook back.
- 9 THE COURT: Thank you.
- 10 Q. Doctor, I'm going to have the Court turn to page
- 11 | 24 of the laboratory notebook. Doctor, after page 24
- 12 | in the laboratory notebook, there are two pages that
- 13 have been removed. Correct?
- 14 A. Correct.
- 15 Q. Can you please explain to me your understanding
- 16 as to why those pages from the laboratory notebook
- 17 | were removed?
- 18 MR. WILLIAMS: Which one are we using, Exhibit
- 19 H? I would ask counsel to identify by the exhibits.
- 20 We're having trouble following, trying to find the
- 21 page.
- 22 MR. LAPINSKI: By the Bates numbers.
- 23 MR. WILLIAMS: Or the exhibit number.
- MR. LAPINSKI: Exhibit H.
- MR. WILLIAMS: Can I ask the page number.

```
MR. LAPINSKI: 24.
1
 2
            MR. WILLIAMS: In the copy we have, your
    Honor, some of the page numbers are legible but some
 3
    are not at the bottom of the page. So we would ask
 4
    that counsel describe the Bates number rather than the
 5
 6
    handwritten page number because those are not legible.
 7
            THE COURT: Okay.
8
 9
    BY MR. LAPINSKI:
10
    Q. Dr. Saed up on the ELMO we have page 24 of your
11
12
    laboratory notebook, which was in Exhibit G, and the
13
    2 pages following page 24 have been removed. Correct?
14
    Α.
          Correct.
15
          Can you please explain your understanding as to
16
    why those pages have been removed?
17
          Your Honor, we have a new hire research
    Α.
    assistant from China, and she was not familiar with
18
    the practice, normal practice of lab notebooks. She
19
    wanted to keep everything related to talcum powder in
20
21
    one notebook. So she started a different project in
22
    those two pages. So she decided to take them out. I
23
    instructed her not to do it. This is very bad
24
    laboratory conduct.
25
          Dr. Saed, I'm going to ask you to make sure you
    Q.
```

Case 3:16-md-02738-FLW-LHG Document 11638 Filed 12/23/19 Page 34 of 276 PageID: Salo4194 irect/Mr. Lapinski 34 1 speak up. 2 Dr. Saed, is it normal lab practice to remove pages from your notebooks? 3 Absolutely not. 4 Α. Doctor, do the missing pages have any 5 Q. substantive effect on the work that you have done? 6 7 No. Α. 8 Q. Why not? They are completely for a different project. 9 Typically, in our lab, your Honor, we have small 10 projects and we have one notebook we used for 11 12 different projects because we divide them into 13 sections. In this one we decided to keep everything related to talcum powder in one place. 14 15 To the extent the pages of the notebook had been removed and those pages had contained a computerized 16 17 data you put into the notebook. Would the removal of those pages have any substantive effect on the work 18 you did? 19 20 Α. No. 21 Why not? Q. 2.2 Α. Because they don't have any data, and they are

- for a different project. 23
- 24 Where is the data for your research maintained? Q.
- 25 They are all maintained in the computer Α.

- 1 electronically.
- Q. Doctor, to the extent the pages that have been
- 3 removed contain handwritten notes on the methodologies
- 4 | that you employed in your research, would that have
- 5 | any substantive effect on the outcome of your results?
- 6 A. Not at all.
- 7 Q. Why is that?
- 8 A. Because all the data is in the computer, and
- 9 they are glued into the lab notebook; and, also, these
- 10 | methodologies, we have done several, many, many, many
- 11 | times, and we are familiar with the methodology. So
- 12 | the lab notebook have no -- we have the data that
- 13 comes from the computer straight to the lab notebook.
- 14 | No one has any influence in the lab nor in the
- 15 | computerized data.
- 16 Q. Dr. Saed, are there certain sections within the
- 17 | notebook where white-out has been used?
- 18 A. Yes.
- 19 Q. Can you please explain your understanding as to
- 20 why certain pages of your notebook have white-out on
- 21 them?
- 22 A. Yes.
- 23 MR. WILLIAMS: May we ask again what notebook
- 24 | is it, G or H?
- MR. LAPINSKI: We are going to end up

referencing H; but in general, there is white-out in parts of section G and white-out in parts of section H.

MR. WILLIAMS: As counsel is going through those, will he identify whether it is G or H.

2.2

BY MR. LAPINSKI:

- Q. Doctor, in Exhibits G and H there are pages that
- 10 | have white-out. Correct?
- 11 A. Yes. Your Honor, this is from the new hired 12 lady.
- 13 THE COURT: Speak up.

THE WITNESS: The new research assistant that we hired has this habit of whiting out spelling mistakes, grammar, because she's embarrassed if we see it. If you look at the white-out, you can see through them. All the white-out is in the writing section, the methodology part that we already have established in the lab with printouts. She has no white-out in the data. All the data is in the computer. She has nothing to do with that. I instructed her this is a bad practice. You cannot white-out stuff. You have to cross it and write over it, and she never did it after that. But all the white-out is in the writing,

- 1 | the methodology part, not in the data part. So it
- 2 | will not have any substantial effect on the data.
- 3 | Q. Dr. Saed, who has ultimate responsibility for
- 4 | the content of these laboratory notebooks?
- 5 A. I do.
- 6 Q. Dr. Saed, did anyone in your lab use white-out
- 7 to change information after your experiments had been
- 8 | completed?
- 9 A. No.
- 10 | Q. Did you or anyone in your lab use white-out to
- 11 change the results in your research?
- 12 MR. WILLIAMS: Objection. Lacks foundation.
- 14 BY MR. LAPINSKI:
- 15 Q. Doctor, are you aware of whether anyone in your
- 16 | lab used white-out to change any results of your
- 17 research?

- 18 A. Your Honor, I have lab notebooks dated 20 years
- 19 ago to now, and I can show there is not one single
- 20 | incident we have white-out in any of those lab
- 21 notebooks. This is just because of this new hire.
- 22 | She wasn't familiar with the practice and she started
- 23 | whiting out; and the white-out you could see through
- 24 | it, and no white-out is in the data. This is just in
- 25 | the methodology. We don't even need to put in the lab

notebook. 1

- 2 Dr. Saed, does the white-out have any Q.
- 3 substantive effect on the results of your research?
- Absolutely not. 4 Α.
- 5 Q. Why not?
- 6 Because all of the data are electronically kept Α.
- 7 with formulas.
- 8 THE COURT: For instance, when you were doing
- your results 24, 48, and 72 hours, was that 9
- electronically kept simultaneously while you were 10
- doing the work? 11
- 12 THE WITNESS: Yes.
- 13 THE COURT: Because there are some indications
- 14 the 48 hours was changed to 72 at some point?
- 15 THE WITNESS: Not in the lab notebook. There
- 16 was an error in the actual manuscript. Your Honor,
- 17 the manuscript -- we have trainees like clinical
- residents and fellows, and we let them participate in 18
- writing, practicing writing a paper and discussing 19
- 20 data and doing graphs. This is part of our mentorship
- 21 practice.
- MR. WILLIAMS: I can't hear him. 2.2
- 23 This is part of our mentorship practice.
- 24 there is an error that's in the manuscript when it
- 25 gets back to me at the last stage, I will make sure I

- check everything and I correct everything according to what's written in the laboratory notebook.

 THE COURT: You would consider that
- significant, the timing, in the experiments?

 THE WITNESS: Yes.
- Q. Dr. Saed, is the timing related to the
 experiment maintained in the computerized data that
 you previously referred to?
- 9 A. The timing of each experiment is logged in in the lab notebook.
- Q. And the data that results from the different experiments that you run at different time intervals,
- 14 A. In the computer.

where is that data stored?

- 15 Q. Is it possible to change the timing that you referred to in your research by using white-out?
- 17 A. No.

13

18

19

20

21

2.2

23

- asked him the question about timing. He said it is in the computer. You just asked him -- you said is the timing related to the experiment; his answer was the timing of the experiment is logged into the lab notebook. It is not quite consistent to me. I want to understand before we go on.
- 25 | Q. Doctor, do you understand the question Judge

```
40
    Wolfson is asking?
1
 2
            THE COURT: Clarify where the timing is
 3
    entered and when it is entered from each of those
    sources, computer versus lab notebook.
 4
            THE WITNESS: I will.
 5
            In the lab notebook, we write "experiment" as
 6
 7
    you see there. We write "cells," what cells we treat;
8
    we list them. What material we use, what type of
 9
    powder we use, and how long we are going to treat.
    Then we run the assay. And in the computer there is a
10
    date -- if you look at the electronic copies you see
11
12
    the dates. There is a date in the electronic copy
    where we run the assay. And then all the data from
13
    the assay is linked to the computer. The computer is
14
15
    exported to the spreadsheet that has all the
    formulas, all the calculations --
16
17
            THE COURT: Who inputs into the computer?
            THE WITNESS: We remove them from the
18
    computer, from the computer that's linked to the
19
20
    machine. We take them in a flash drive. We put them
21
    in the main computer of the lab, and we transfer,
22
    export the data to the spreadsheet.
23
            THE COURT: I'm asking how it appears on the
24
    computer. I just want to understand what your
25
    testimony is.
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Is what you are saying, that this assay -what's actually being done on there is somehow on the machine also reflecting the timing, and that is on a flash drive that gets put into the computer or no? THE WITNESS: No. THE COURT: So I'm not understanding your testimony. Dr. Saed, can you clarify in regard to the different treatment times, 24, 48 and 72 hours, how those treatment times are recorded? THE COURT: How they are recorded into the computer. He's already said they go into the lab notebook, and I think you answered those are entered into the lab notebook at the time that the experiment is occurring, not after the fact. Is that correct? THE WITNESS: We enter them into the lab notebook. THE COURT: When? THE WITNESS: When we start the experiment. We write the conditions, the cells, how long they are going to be exposed for, the time, what are the doses we are going to use, and we write this down. We go and do the experiment. We print the printout of the

experiment from the computer, from the spreadsheet; we

print it out and stick it next to those sections where

```
first page in Exhibit H?
1
 2
    Α.
          Yes.
 3
            MR. LAPINSKI: Your Honor, I believe in the
    laboratory notebook that would be page 28, I believe.
 4
    In that notebook, your Honor --
 5
            THE COURT: Somewhere down the line when I
 6
 7
    have to look at this record I would have no idea what
8
    pages you are referring to if you are giving me the
 9
    lab notebook versus Exhibit H. Maybe the best thing,
    let's refer to the exhibits.
10
            MR. LAPINSKI: In your binder, Exhibit H in
11
12
    your binder, the first page, Exhibit H in your binder.
            THE COURT: It is a picture of Johnson's --
13
          Dr. Saed, I asked you the question whether or
14
    0.
15
    not Johnson's Baby Powder had been used in the
    experiments that you had conducted, and you said yes.
16
17
    Can you explain to me how you can be sure it was
    Johnson's Baby Powder that was used?
18
          This section of the lab notebook, all the work
19
    is done with Johnson & Johnson Baby Powder, and
20
    usually we describe the cell lines that we are going
21
```

to use and where do they come from, and we put a

picture and lot number of the Johnson & Johnson Baby

MR. LAPINSKI: Judge Wolfson, do you have any

22

23

24

25

Powder that we used.

- questions in regard to sections in the lab notebook that might have had white-out?
- THE COURT: Without going to specific pages.
- 4 | I have his general testimony of what occurred saying
- 5 | it was due to errors by a new lab assistant who didn't
- 6 understand how to do things, and his view was none of
- 7 it was substantive. I'll wait for cross-examination
- 8 on particular ones. I'll wait for that.
- 9 Q. Dr. Saed, I would like to be able to discuss
- 10 | with you the methodologies you employed while
- 11 | conducting your research.
- In your opinion, are the methodologies you
- 13 used in conducting your research generally accepted?
- 14 A. Yes.
- 15 Q. Can you please explain that?
- 16 A. As I said, in my research I used realtime PCR,
- 17 | ELISA, MTT proliferation assay, apoptosis assay, cell
- 18 death assay, and all the assays, your Honor, I just
- 19 | listed, these are very well established assays
- 20 | methodologies, well used by the research community in
- 21 hundreds, maybe thousands of papers.
- 22 | Q. Doctor, did you publish on the same methods you
- 23 | used in your Johnson & Johnson Baby Powder recently?
- 24 A. Yes.
- 25 | Q. The methods you used in the research of Johnson

4.5

- 1 & Johnson Baby Powder, how many times do you think you
- 2 | have published on those methods?
- 3 A. I'll say over a hundred-plus publications.
- 4 Q. Are there others in the scientific community
- 5 | that published using those same methods?
- 6 A. Yes.
- 7 Q. How many times do you think others have
- 8 | published on research using the methods you used in
- 9 your Johnson's Baby Powder research?
- 10 A. This is a -- these are common methodologies.
- 11 | Everybody in cell biology and biochemistry uses them,
- 12 everybody.
- 13 Q. Are you aware of other researchers who published
- 14 | using methods similar to the methods you used where
- 15 | the publications dealt with research on talcum powder?
- 16 A. Yes.
- 17 Q. Doctor, I would like to discuss several
- 18 different aspects of your research design and methods.
- 19 First, Doctor, have you done testing on
- 20 particles applied to cell cultures in the past?
- 21 A. Yes.
- 22 | Q. Can you give me some examples of testing done on
- 23 | particles involving cell cultures?
- 24 A. I was hired by Genzyme to test their product
- 25 | Seprafilm.

They asked me to test the particulate, their 1 2 product, they used to prevent or minimize 3 postoperative adhesions. Those adhesions happen in women after caesarean sections, and I tested the 4 product, and we used the exact same methodology that 5 we used to test Johnson & Johnson Baby Powder, and I 6 7 found out that their product does not induce any 8 biological activity, and it works by -- simply as a film barrier between juxtaposed surfaces. 9 Was it testing of the Seprafilm product you 10 referred to? During that testing did you employ the 11 12 same methods you employed in testing Johnson's Baby Powder? 13 14 Α. Yes. 15 Was your testing published? Q. 16 Α. Yes. 17 MR. WILLIAMS: Objection to the extent this is not contained in the doctor's report, at least as far 18 as I know. The testimony regarding the other company 19 and the other products. 20 21 MR. LAPINSKI: The publications Dr. Saed is 2.2 referring to are contained in the CV attached to his 23 expert report. 24 THE COURT: The question is, did he anywhere 25 indicate he used this method before, and he was

2.2

questioned about it at his deposition, and I take it that was not part of the testimony.

MR. LAPINSKI: The testimony at -- the testimony at his deposition was that he couldn't recall specific instances. He did recall one instance during his deposition that he had tested on particles and cell cultures, but at the time of his deposition he wasn't able to recall others.

Again, your Honor, the publications -- the testing and research we are referring to right now are publications contained in his CV and disclosed as work he had done.

MR. WILLIAMS: As I understand, what counsel is saying, it is not indicated in Dr. Saed's report that either the company or the material, the product was tested. He was asked about it at his deposition and could not recall. He could not list any. So we will ask to strike testimony concerning some prior testing for another company with another product to reach a particular result to the extent it is not in the report.

THE COURT: He certainly didn't have an opportunity to explore it because he didn't identify it before.

Let's move on, please.

BY MR. LAPINSKI: 1

2 Q. Dr. Saed, the test methods that you employed in

- 3 testing Johnson's Baby Powder, have you used those
- similar test methods to test particles in cell 4
- cultures in the past? 5
- 6 Α. Yes.
- 7 That testing that you have done, have you been
- 8 published on that testing?
- 9 Α. Yes.
- How many different times have you been published 10 Q.
- on that form of testing? 11
- 12 Over maybe 100 manuscripts.
- Dr. Saed, is the testing of particles in cell 13 Q.
- cultures that you've done in the past published? 14
- 15 Α. Yes.
- 16 Dr. Saed, are you aware of others who have Q.
- 17 published on the testing of particles in cell cultures
- using the same methods you employed in your Johnson's 18
- Baby Powder research? 19
- 20 Α. Yes.
- 21 Dr. Saed, are the methods used by you in your Q.
- 22 Johnson's Baby Powder research to test particles in
- cell cultures generally accepted? 23
- 24 Α. Yes.
- 25 Dr. Saed, I want to talk to you about your use Q.

- 1 of controls during your testing. Could you explain to
- 2 | the Court what a control is?
- 3 A. A control is a vehicle that we use in order to
- 4 determine if the effect of the agent that we are
- 5 treating is due to the agent and not due to another
- 6 artifact.
- 7 Q. In basic terms, can you give us an example of a
- 8 | control?
- 9 A. What I could think of right now, the best
- 10 example would be the placebo control when we are
- 11 | testing the effect of drugs.
- 12 | Q. Doctor, did you use the control in the research
- 13 | you constructed?
- 14 | A. I did.
- 15 Q. What was the control you used?
- 16 A. Talcum powder dissolved in DMSO and DMSO alone.
- 17 Q. For what reason did you opt to use DMSO?
- 18 A. DMSO is an organic solvent commonly used in
- 19 research studies, and I used it in the past and other
- 20 | people have used it.
- 21 Q. Have you used it in the past in research that
- 22 | has been published?
- 23 A. Yes.
- 24 | Q. Are you aware of others who used DMSO for
- 25 research that has also been published?

- 1 A. Yes, several, many.
- 2 Q. Would you consider DMSO to be generally accepted
- 3 by the scientific community?
- 4 A. Yes.
- 5 Q. Doctor, I want to talk to you about the doses
- 6 you chose to use during the testing of your Johnson's
- 7 Baby Powder. What were the doses of talc that you
- 8 used as part of your research?
- 9 A. I used zero, five, 20 and 100-micrograms per
- 10 milliliter.
- 11 | Q. How did you come to the decision to use those
- 12 doses?
- 13 A. Those doses are published, similar to these
- 14 doses are published in the literature that talk about
- 15 | testing talcum powder and determining whether the
- 16 powder has a biological effect in cells.
- 17 Q. Did those published papers play a role in your
- 18 decision as to the doses you used in testing Johnson's
- 19 | Baby Powder?
- 20 A. It helped me to make sure I am in the right
- 21 range of doses and not using excessive dose that may
- 22 kill the cell.
- 23 Q. Dr. Saed, are you familiar with the scientific
- 24 | concept of testing in triplicate?
- 25 A. Yes.

- Q. Can you explain that concept to the Court?
 A. Triplicate, your Honor, in cell culture as we do
- 3 it. We do it in one way to take one cell, one plate,
- 4 and divide it into three different plates, and that's

5 considered the triplicate.

2.2

The other way which I like to do in cases like this is to, instead of getting one cell line, divide it into three, I got six different cell lines and I used them.

So if you find the effect, the same effect that we found with talcum powder in six different cell lines, it will be way more powerful than finding this effect in one cell line split into three.

THE COURT: That's not testing in triplicate?

THE WITNESS: It is. It is testing more than triplicate. We tested six different cell lines.

THE COURT: The way you explained the first one, that's not what you are doing here. What's supports your basis for doing it in this way?

THE WITNESS: When I did have it here, I've decided to do it testing it in six different cell lines rather than one cell line doing it three times.

THE COURT: Then you are not repeating it.

You are doing different cell lines and not repeating it three times with those cell lines?

- THE WITNESS: The experiments are all done in
- 2 | triplicate, your Honor. The effect that you see in
- 3 | three normal, different normal is more powerful than
- 4 | the same effect that you see in one normal three
- 5 times. I published both ways.
- 6 Q. Doctor, you've conducted experiments using both
- 7 designs that you discussed here. Correct?
- 8 A. Yes.
- 9 Q. And you published using designs of triplicate
- 10 | that you used here?
- 11 A. Yes.
- 12 | Q. Are you aware of others that have been published
- 13 using the second form of triplicate that you used here
- 14 | with Johnson's Baby Powder that have been published?
- 15 A. Yes.
- 16 Q. Doctor, if someone wanted to, how would they go
- 17 about reproducing the research that you did?
- 18 A. They can read the manuscript, look at the
- 19 | methodology part and replicate it.
- 20 Q. Are the testing methods that you used in testing
- 21 Johnson's Baby Powder established testing methods?
- 22 A. Yes.
- 23 | Q. If someone were to take the manuscript that you
- 24 used, referred to, and applied those general testing
- 25 | methods, they would be able to reproduce the research

- 1 that you did?
- 2 A. Yes.
- 3 Q. I want to discuss with you the markers that you
- 4 | used in analyzing Johnson's Baby Powder. What were
- 5 | the five different markers that you looked at?
- 6 A. We looked at redox balance. We looked at CA-125
- 7 levels. We looked at cell proliferation. We looked
- 8 at apoptosis. We looked at gene mutations in key
- 9 enzymes that regulates the redox balance.
- 10 | Q. Why did you choose these particular markers?
- 11 A. So these markers will provide the overall
- 12 picture of cells going into the transformation mode,
- 13 and also these are all well known experiments to us.
- 14 We have previously published with them. They are
- 15 | within the expertise of my lab. We have done over 50
- 16 | publications with this different testing in ovarian
- 17 | cancer specifically.
- 18 Q. Are you aware of others outside of your lab that
- 19 used these markers and tested for ovarian cancer using
- 20 | these markers?
- 21 A. Yes.
- 22 | Q. Are you aware of others who published using
- 23 | these markers?
- 24 | A. Yes.
- 25 Q. Would you consider the use of these markers to

Salo4214 irect/Mr. Lapinski

be generally accepted? 1

- 2 Α. Yes.
- 3 Doctor, I would like you to describe the
- specific experiments you chose to use in order to test 4

- each marker. 5
- 6 If you look, your Honor, at the screen, we Α.
- 7 measured several processes. We measured the redox
- 8 balance. For this we used realtime PCR, which is a
- 9 well-establish technique by the research community and
- ELISA, which is a well-established technique. We used 10
- CA-125. We used ELISA to measure that, and that's a 11
- 12 very, very common technique. We used the MTT cell
- 13 proliferation assay, which is a very commonly used
- 14 assay to measure cell divisions, and we used Caspase 3
- 15 activity, which is an indicator of cells going through
- 16 apoptosis, which is -- and we used Taqman, again, type
- which is a very common assay looking at certain, 17
- again, mutations and enzymes on proteins. 18
- Doctor, were there other experiments you could 19
- have chosen in order to test each marker? 20
- 21 Α. Yes.
- 22 Is it necessary to run every available Q.
- 23 experiment for you to make determinations regarding
- 24 the effect of talcum powder on these various markers?
- 25 Α. No.

- 1 | Q. Why did you choose these particular experiments?
- 2 A. Your Honor, these are very well established
- 3 | methodologies in my lab, and we feel very confident
- 4 | with these methodologies.
- 5 Q. Doctor, in addition to them being very well
- 6 established in your lab, are you aware of others who
- 7 have used these experiments?
- 8 A. Yes.
- 9 Q. Are you aware of others who have been published
- 10 using these experiments?
- 11 A. Yes.
- 12 | Q. Would you consider these experiments to be
- 13 | generally accepted?
- 14 A. Yes.
- 15 Q. Doctor, could you please explain to the Court
- 16 | what "altered redox balance" means?
- 17 A. Redox balance, your Honor, you have two groups
- 18 of enzymes that regulate the overall oxidant balance:
- 19 The enzymes that cause oxidation and the enzymes that
- 20 remove oxidation, and the balance between the two is
- 21 redox balance. This balance is very critical
- 22 | especially for ovarian cancer development. We have
- 23 | published several papers showing this is a hallmark of
- 24 | ovarian cancer pathogenesis.
- 25 Q. Dr. Saed, what did your research find in regard

1 to redox balance?

- 2 A. We found that ovarian cancer cells have enhanced
- 3 as we characterized previously, enhanced oxidative
- 4 stress balance. They have enhanced prooxidant state.
- 5 What my research showed here, that if you treat normal
- 6 cells with Johnson & Johnson Baby Powder, you get a
- 7 | huge increase in a dose response manner in oxidants.
- 8 This side here is oxidants. This is a huge increase
- 9 | compared to control, and this accompanied with a
- 10 decrease in antioxidants.
- 11 We confirmed this finding, your Honor. We
- 12 | didn't do just PCR one assay, one RNA. We confirmed
- 13 | the data at the RNA level and the protein level and
- 14 | activity level in both tests.
- 15 Q. Doctor, could you please explain to the Court
- 16 | what apoptosis is?
- 17 | A. Apoptosis is a program cell death. It is a
- 18 | natural process that occurs in the body that
- 19 | eliminates bad cells that we develop every single
- 20 | minute in our body.
- 21 Q. Can you explain to the Court what proliferation
- 22 is?
- 23 A. Proliferation is cell division, but in cancer
- 24 | cell division which is uncontrolled. So the cells
- 25 | keep dividing without control mechanism.

- 1 | Q. What did your testing of Johnson's Baby Powder
- 2 | find as it relates to apoptosis and proliferation?
- 3 A. We found an increase in proliferation in
- 4 uncontrolled cell division and decrease in apoptosis.
- 5 | These two processes, your Honor, are strong indicators
- 6 of cells on their way to transformation.
- 7 Q. Doctor, what is gene mutation?
- 8 A. It is a switch in the nuclear type in the DNA.
- 9 Q. What is the significance of gene mutation as it
- 10 relates to ovarian cancer?
- 11 A. Gene mutations occur in almost all cancers that
- 12 | we know.
- 13 | Q. What did you find out about gene mutation in
- 14 | your research related to Johnson's Baby Powder?
- 15 A. Your Honor, we found that if you expose normal
- 16 | surface epithelial cells from the ovary to talcum
- 17 | powder 100 micrograms per mill for 72 hours, you get a
- 18 | switch in the genome in the DNA sequence that
- 19 | corresponds to these key enzymes that regulate the
- 20 redox balance, and that's very, very significant
- 21 because it alters -- now we can understand the
- 22 | mechanism by how Johnson & Johnson Baby Powder
- 23 | inducing these mutations that changes the activity of
- 24 | these enzymes that are key players keeping the oxidant
- 25 redox balance.

- 1 Q. Doctor, is there a difference between gene
- 2 mutation and cell transformation?
- 3 A. Usually gene mutation is before transformation.
- 4 It is very early process. It happens every day, and
- 5 | we have apoptosis in our bodies that eliminate mutated
- 6 cells or bad cells. But gene mutation is a very early
- 7 process and it is followed by transformation.
- 8 Q. In the research you conducted related to
- 9 | Johnson's Baby Powder, did your experiments find cell
- 10 transformation?
- 11 A. No, I did not test for actual cell
- 12 | transformation, but I tested for cell proliferation
- and apoptosis which are accepted as strong indicators
- 14 of cells going transformation.
- 15 Q. Doctor, what is your opinion as it relates to
- 16 | Johnson's Baby Powder and cell transformation?
- 17 A. I think the fact that Johnson & Johnson Baby
- 18 | Powder was able to induce mutations in key oxidant
- 19 enzymes and antioxidant enzymes and altering their
- 20 activity and changing the overall redox balance in a
- 21 | way that limits exactly what we have studied for
- 22 | several years. Ovarian cancer profile is very
- 23 | significant. It is an indication cells are going in
- 24 | this direction.
- 25 Q. Doctor, that opinion that you are offering, is

- 1 | that opinion based solely upon the research you did
- 2 related to Johnson's Baby Powder?
- 3 A. Yes, it is part of it, and the research we did
- 4 here and also in our 25 years experience, your Honor,
- 5 | with oxidative stress and ovarian cancer.
- 6 Q. Dr. Saed, what is CA-125?
- 7 A. CA-125 is a marker of -- it is a cancer antigen
- 8 | gene, a protein that is increased in cancer cells.
- 9 Q. Why did you test for CA-125?
- 10 A. It is considered a marker for ovarian cancer for
- 11 | a doctor when they monitor patient response to
- 12 therapy.
- 13 | Q. What did your testing of CA-125 show?
- 14 | A. It shows that if you treat cells with
- 15 | 100 micrograms per ml for 72 hours, you will see a
- 16 | significant increase in CA-125, indication of
- 17 inflammation.
- 18 Q. Doctor, what cell lines did you use in the
- 19 experiments that you ran?
- 20 A. Your Honor, we used three different ovarian
- 21 | cancer cells and we used one normal epithelial
- 22 | Fallopian tube cells and one normal primary ovarian
- 23 | epithelial cells and as a control for nonepithelial
- 24 | cell origin.
- 25 Q. Doctor, how was it that you decided to use these

cell lines? 1

- 2 A. These cell lines we have experience, we
- 3 published with them several times. They are well
- known to us in our lab, and we know their oxidative 4
- 5 stress profile.
- Q. Are you aware of others who have published using 6
- 7 these cell lines?
- A. Yes. 8
- Q. Doctor, could you have used just a single cell 9
- line in your research? 10
- Yes. Α. 11
- 12 Q. Why did you choose not to use a single cell
- line? 13
- A. It is more powerful to show the effect in 14
- various cells than just one cell line. 15
- Q. Dr. Saed, I would like you to turn in your 16
- binder to Exhibit SAED OPP Exhibit F. 17
- 18 MR. LAPINSKI: That's toward the back, your
- 19 Honor.
- Q. Dr. Saed, what is it that we are looking at that 20
- has been marked as SAED OPP Exhibit F? 21
- 22 A. We are looking at hypothesis-driven proposal --
- 23 budget.
- 24 Q. Dr. Saed, who prepared this budget?
- 25 A. I did.

- 1 Q. Why did you prepare this budget?
- 2 A. Your Honor, before we start any project in our
- 3 | lab, because we have many trainees and many research
- 4 | assistants, we outline the project in a hypothesis-
- 5 driven research, because most of our projects end up
- 6 submitting to agencies for funding, and also for the
- 7 | people in the lab to know the outline of the project,
- 8 and for us to know how much it will cost to run the
- 9 project.
- 10 Q. Doctor, you used the phrase "hypothesis-driven
- 11 | budget." Can you please explain what you mean by
- 12 that?
- 13 A. Hypothesis-driven research, I've been doing this
- 14 | for the last 25 years or more. When you write a grant
- 15 to agencies like federal agencies, for example, like
- 16 NIH or NCI, they have a format you should follow, and
- 17 | I got the habit of following this format, which is the
- 18 | hypothesis rationale -- what are your expected
- 19 | results, what do you expect to get; if you don't get
- 20 what you expect to get, what is your alternative
- 21 approach, and what is your future direction.
- 22 I got into this habit of writing that all the
- 23 time.
- 24 | Q. If we could, Doctor, what was the objective of
- 25 | the research that you stated in your budget?

- 1 A. So here the objective is to determine whether
- 2 talc can induce mutations in key redox enzymes. These
- 3 | mutations are responsible and they contribute to the
- 4 development of the oncogenic phenotype. It is
- 5 | becoming cancerous.
- 6 Q. Doctor, could you please explain what you mean
- 7 by "oncogenic phenotype"?
- 8 A. Cell becoming cancer.
- 9 Q. At the time you prepared this budget, did you
- 10 | think whether talc could induce mutations as you've
- 11 | stated in your objective?
- 12 A. No.
- 13 Q. If we could go to the second page of this.
- Doctor, this is Aim 1 on page 2 of your
- 15 proposal. Could you explain to the Court how Aim 1 is
- 16 structured in accordance with the hypothesis-driven
- 17 | budget you were previously explaining?
- 18 A. In Aim 1 we wanted to determine whether exposing
- 19 cells to talc will change the overall oxidative stress
- 20 | balance, and looking at key markers of oxidation and
- 21 key markers of anti-oxidation.
- 22 | Q. Is that the hypothesis?
- 23 A. Yes.
- 24 Q. You also mentioned a rationale part of the
- 25 | hypothesis-driven budget. Correct?

- 1 A. Yes.
- 2 | Q. In the image you are looking at Aim 1, what part
- 3 of that would be the rationale that you are referring
- 4 to?
- 5 A. That we have seen these changes linked to
- 6 ovarian cancer in previously published work that we
- 7 have done and others did, and we are looking at the
- 8 | specific markers that are key regulators of oxidative
- 9 stress and inflammation, and we expect -- this is just
- 10 as I mentioned, your Honor -- this is just a way we
- 11 | write for granting agencies.
- 12 | Q. Doctor, are you aware of others who prepared
- 13 grants that were submitted to agencies that employed
- 14 | the same format you used in this budget?
- 15 A. Yes. Everybody has to use this format.
- 16 Q. Doctor, in addition to the hypothesis and
- 17 | rationale sections, you also mentioned there is an
- 18 expectation that's part of the hypothesis-driven
- 19 budget. Correct?
- 20 A. Yes.
- 21 Q. Do you have an expectation section that's
- 22 demonstrated here in this aim?
- 23 A. Yes. Expectation doesn't mean this is what I
- 24 | want to get. It means based on the results would show
- 25 positive, this is what we would get, and then we would

- 1 have to have a alternative approach if our approach
- 2 doesn't work.
- 3 Q. Is it standard practice when preparing this type
- 4 of hypothesis-driven budget and submitting a grant to
- 5 | an agency to state what your expectations of your
- 6 research are?
- 7 A. Yes.
- 8 | Q. In all three aims in your budget did you include
- 9 | a hypothesis, a rationale, and an expectation?
- 10 A. Yes.
- 11 Q. I would like to go to Aim 3 that's contained in
- 12 your budget.
- Doctor, in looking at Aim 3 that's contained
- 14 | in your budget at the bottom in the expectations,
- 15 | what's the expectation you have in Aim 3, Doctor?
- 16 A. We expected to see if you treat cells with
- 17 | talcum powder, they will result in neoplastic
- 18 transformation over time. That's our expectation.
- 19 Q. Doctor, does that sentence note anything else in
- 20 regard to neoplastic transformation?
- 21 A. Yes, which is critical in establishing cause and
- 22 effect relationship.
- 23 | Q. Did you run a neoplastic transformation assay in
- 24 your research?
- 25 A. No, I did not.

- 1 | Q. Is a neoplastic transformation assay necessary
- 2 to support the opinions you are providing here?
- 3 A. No.
- 4 Q. Why is that?
- 5 A. Your Honor, as I mentioned, I have done cell
- 6 proliferation and apoptosis, and both are accepted as
- 7 strong indicators of cells going through the
- 8 transformation process.
- 9 Q. Doctor, the research that you did related to
- 10 | Johnson's Baby Powder, has that been reviewed by
- 11 | independent experts?
- 12 A. Yes.
- 13 Q. I would like to be able to walk through the
- 14 | reviews that have been conducted by independent
- 15 experts if we could.
- Doctor, if you look at the screen, what's the
- 17 | first time the research that you conducted related to
- 18 talcum powder was reviewed by independent experts?
- 19 A. The first time is the abstract that we submitted
- 20 | to the 65th annual meeting of the Society For
- 21 Reproductive Investigation. This work is looking at
- 22 | the effect of exposing cells to talc and looking at
- 23 | the oxidative stress profile of the cell.
- 24 | Q. Doctor, what is your understanding as to the
- 25 | number of experts that would review that abstract

- 1 | prior to it being accepted for presentation?
- 2 A. Typically, they are reviewed by four to six
- 3 experts.
- 4 Q. When is the next time that your work was
- 5 reviewed by independent experts, Doctor?
- 6 A. We submitted to the same meeting another
- 7 abstract looking at the levels of CA-125 in response
- 8 | to talcum treatment of cells. This is also reviewed
- 9 by four to six experts in the field.
- 10 MR. WILLIAMS: We object to the lack of
- 11 | foundation for the abstracts as to how many experts
- 12 reviewed.

- 14 BY MR. LAPINSKI:
- 15 Q. Doctor, have you previously served as a reviewer
- 16 | for the Society of Reproductive Investigation?
- 17 A. Yes, I did.
- 18 Q. In your experience as a reviewer for the Society
- 19 of Reproductive Investigation, how many experts will
- 20 | commonly review abstracts submitted for presentation?
- 21 A. Four to six.
- 22 THE COURT: Is that what you are basing your
- 23 | testimony on, your past experience?
- THE WITNESS: Yes.
- THE COURT: You don't know for a fact how many

- 1 A. It is reviewed by two reviewers.
- 2 Q. Can you identify what's on the screen?
- 3 A. This is a letter from Gynecologic Oncology
- 4 stating they will not be able to accept my work at
- 5 this moment.
- 6 MR. LAPINSKI: For the record, the exhibit
- 7 | that's now showing on the screen is in the binder and
- 8 | it is PSC Saed OP Exhibit M.
- 9 Q. Dr. Saed, did you receive feedback from the
- 10 | independent experts at Gynecologic Oncology with
- 11 regard to the manuscript that you had submitted?
- 12 A. Yes.
- 13 Q. I would like to first look at the feedback you
- 14 | reviewed from Reviewer No. 1. What were the comments
- 15 | that Reviewer No. 1 made in regard to the manuscript
- 16 | that you submitted?
- 17 A. The first comment from Reviewer 1, it says that
- 18 Overall, this is a well-written manuscript, and the
- 19 | conclusions are supported by the results."
- 20 0. What are other comments that Reviewer No. 1
- 21 made?
- 22 | A. Reviewer No. 1 suggested to enhance the study by
- 23 utilizing mouse models.
- 24 Q. In your opinion do you need animal studies to
- 25 | support the opinions you are providing here today?

1 Α. No.

- 2 If animal studies were done, would the animal Q.
- 3 study corroborate the work that you have done?
- Yes. I have to say, your Honor, cell culture is 4 Α.

- 5 the gold standard for testing mechanisms if you are
- looking at the effect of an agent on cell functions. 6
- 7 Dr. Saed, if we look at comment No. 3, and if Q.
- 8 you could just read what comment No. 3 from Reviewer 1
- 9 was?
- 10 A. It says:
- "Oxidative stress is a key mechanism to the 11
- 12 initialization and progression of ovarian cancer.
- 13 This is not supported by this investigation and should
- be omitted." 14
- 15 The quotation there, that's a quotation you had
- 16 in the manuscript that you submitted. Correct?
- 17 Α. Yes.
- And Reviewer No. 1 here is stating the opinion 18
- that it's not supported by your research? 19
- 20 Α. Yes.
- 21 Do you agree with that comment, Doctor? Q.
- 2.2 Α. No.
- 23 Why don't you agree with that comment? Q.
- 24 Because in the same journal I published a review Α.
- 25 article, and this statement was the actual highlight

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                            salo4230 irect/Mr. Lapinski
                                                                  70
          from that article, take-home message.
      1
      2
                Doctor, I would like to take a look at the
          Q.
      3
          comments --
                  THE COURT: What is the review article?
      4
                  MR. LAPINSKI: Excuse me, your Honor?
      5
                  THE COURT: What is a review article?
      6
      7
                  THE WITNESS: A review article is usually
      8
          written by experts in the field for the journal.
                                                              Ιt
          is a peer-reviewed, published review article.
      9
                  THE COURT: I'm not sure what that means.
     10
                  THE WITNESS: It is an article that's a review
     11
     12
          article. The review article is reviewed by the same
     13
          process but usually it's from experts in the field
     14
          opposed to -- as opposed to just a regular manuscript.
     15
                Doctor, is it your understanding, based upon
     16
          your experience and serving as a peer reviewer for
     17
          various journals, that those who write review articles
          are usually invited to write the review article?
     18
     19
          Α.
                Yes.
                Is it your understanding that those who are
     20
          invited to write a review article are usually invited
     21
     2.2
          because they are experts in the field?
     23
          Α.
                Yes.
```

24 Doctor, we have up on the screen the

25

February 2017 review article that we previously

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71
    referenced that was published in Gynecologic Oncology
1
 2
    which is the same journal you initially submitted your
 3
    manuscript to. Correct?
 4
    Α.
         Yes.
 5
            THE COURT: This was published before the one
 6
    that was declined. Correct?
 7
            MR. LAPINSKI: That's correct.
8
            THE COURT: This is 2017. His publication
    that was declined was 2018?
 9
            THE WITNESS: Yes.
10
          Doctor, what is the first highlight of the
11
    Q.
12
    review article you published in 2017?
13
    Α.
          "Oxidative stress plays an essential role in the
    pathogenesis of ovarian cancer."
14
15
            That's the take-home message.
16
          That take-home message from your February 2017
    Q.
17
    review article that was published in Gynecologic
    Oncology. In your opinion what is the difference
18
    between that take-home message and what Reviewer No. 1
19
20
    said is not present in the manuscript that you are
21
    submitting?
          There is no difference.
2.2
    Α.
23
          You've previously been published on the topic
24
    that Reviewer 1 said is not supported. Correct?
25
    A. Correct.
```

Q. If we could take a look at the comments of Reviewer No. 2.

THE COURT: My understanding is, what they were saying is that -- in this criticism was that that statement, however, was not supported by this particular investigation or study. That's what the statement is as opposed to a general proposition which was, I guess, the highlight in the first article. They are referring to the actual investigation that underlies the article. Correct? Isn't that what the criticism is?

12 THE WITNESS: Yes.

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- Q. Dr. Saed, a question I would have for you is, first, do you agree with the comments that Reviewer No. 1 had in regard to your statement that oxidative stress is a key mechanism in the initiation and the progression of ovarian cancer, is not being supported by your investigation?
- 19 A. No, I disagree.
- 20 Q. Doctor, have you previously researched and 21 published on that issue?
- 22 A. Yes, I did.
- Q. Doctor, in your opinion, the research, the manuscript that you submitted did support that

25 statement?

Α. Yes.

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2.2

23

24

25

Your Honor, the same reviewer is commenting, saying that the conclusions are supported by the results.

Dr. Saed, we are now going to the comments of Reviewer No. 2.

THE COURT: That's a general comment because it says -- I don't want to argue with the witness. But it just says, the current in vitro study does involve novel information, but there are some important limitations described below, and one was the third criticism. I don't think you take the first statement in the reviewer's comments in a vacuum.

MR. LAPINSKI: Understood, your Honor.

Dr. Saed, what were the comments of Reviewer No. Q.

2? 16

> The Reviewer No. 2 basically is saying that my Α. work with talcum powder will be enhanced if we could show transformation evidence, of cell transformation.

And he suggested to show cell transformation, at least 20 21

to do cell proliferation and apoptosis assays.

Q. Dr. Saed, what did you do as a result of the comments that were provided by Reviewer No. 2?

I was doing a cell proliferation and apoptosis, and I combined the data on my cell proliferation and

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74
    apoptosis, and I resubmitted the whole thing to
1
 2
    Reproductive Sciences.
 3
          You resubmitted your manuscript including
    Q.
    research you had done on cell proliferation and
 4
    apoptosis?
 5
    Α.
 6
         Yes.
 7
    Q.
          That's what Reviewer No. 2 recommended that you
 8
    do?
          They recommended cell proliferation and
 9
    Α.
    apoptosis.
10
         Was the manuscript your submitted to
11
    Q.
12
    Reproductive Sciences accepted for publication?
13
    Α.
         Yes.
          Was that manuscript published?
14
    Ο.
15
    Α.
          Yes.
          When that manuscript was submitted to
16
    Q.
17
    Reproductive Sciences for publication, was that
18
    manuscript and the work you had done reviewed by
    experts?
19
20
    Α.
          Yes.
21
          What is your understanding as to the number of
    Q.
    experts that would have reviewed your work at that
22
23
    time?
24
    A. At least two.
25
            THE COURT: Did you go back and do further
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- 1 the results of your research for further consideration
- 2 and publication?
- 3 A. Yes. We submitted an abstract to the 50th
- 4 | annual meeting of Society of Gynecologic Oncology, and
- 5 this is looking at the effect of Johnson Baby Powder
- 6 on gene mutation.
- 7 Q. That submission, Doctor, to your understanding,
- 8 how many experts reviewed that submission prior to it
- 9 being accepted?
- 10 A. My understanding, abstracts are reviewed at
- 11 | least by four experts in the field.
- 12 Q. Doctor, did you present or did you submit for
- 13 expert review and consideration your research another
- 14 time?
- 15 A. Yes. Also, I presented my work in the 66th
- 16 | annual meeting of Society of Reproductive
- 17 | Investigation, which was held in Paris last March, and
- 18 | this work was also reviewed by at least four experts
- 19 | in the field.
- 20 THE COURT: Is this the same as the poster
- 21 | that's mentioned or is this something different?
- THE WITNESS: The last two?
- 23 THE COURT: I know in reading the materials
- 24 | there was something about the 50th annual meeting, and
- 25 | it was talking about a poster being submitted. I want

- 1 to make sure I have the right things in mind.
- 2 Q. Dr. Saed, in regard to your submission to the
- 3 | Society of Gynecologic Oncology, could you please
- 4 explain to the Court the process of the submission and
- 5 | how the poster presentation plays into that
- 6 submission?
- 7 A. Your Honor, this is an abstract that's submitted
- 8 to the Society of Gynecologic Oncology meeting in
- 9 | Honolulu in March, and it was presented by Dr. Harper,
- 10 | a fellow in my lab, and it is about the effect of
- 11 | talcum powder, Johnson & Johnson Baby Powder, on gene
- 12 | mutations. It was a poster, yes.
- 13 Q. Doctor, could you please explain to the Court
- 14 | the relevance of your research being presented as a
- 15 poster at the meeting as compared to it being accepted
- 16 as an abstract?
- 17 A. Most abstracts get accepted and the reviewer
- 18 | will decide the method of presentation. They either
- 19 | give you an oral presentation or poster presentation.
- 20 MR. LAPINSKI: For the record, the poster
- 21 presentation that relates to the March 2019 SRI
- 22 meeting, is in your binder, and it is marked as PSC
- 23 | Saed 3?
- 24 THE WITNESS: That's the cell proliferation
- 25 and apoptosis.

- 1 Q. Dr. Saed, since the time that you started your
- 2 research related to talcum powder, how many
- 3 | independent experts have reviewed your work?
- 4 A. I would say at least 20.
- 5 | Q. Have any of those experts questioned the
- 6 methodology that you employed in conducting your
- 7 research?
- 8 A. No.
- 9 Q. Have any of those experts criticized the
- 10 methodologies you used in conducting your research?
- 11 A. No.
- 12 Q. Dr. Saed, do you believe that the work that you
- 13 | did is subject to any conflicts that need to be
- 14 | disclosed?
- 15 A. No.
- 16 Q. Why is that?
- 17 A. I don't believe I have a potential financial
- 18 | interest from this work. So I don't think there is a
- 19 | conflict of interest. I checked with the Society of
- 20 Gynecologic Oncology, and I checked with SRI, and when
- 21 you submit abstracts, you are not required to submit a
- 22 | conflict of interest. I actually called them by phone
- 23 and checked and made sure I'm doing the right thing,
- 24 and I asked them -- I'm doing this as part of this
- 25 litigation. I'm doing this work in my lab. Is this

- 1 considered a conflict of interest? My understanding,
- 2 | they explained to me, the conflict of interest is when
- 3 | you have a commercial entity that will fund your lab
- 4 | to develop a product that you have a potential
- 5 financial interest in it.
- 6 Q. Dr. Saed, who paid for the research that you
- 7 | conducted related to Johnson's Baby Powder?
- 8 A. My lab.
- 9 O. Dr. Saed, if your research had shown that there
- 10 | was no biologic activity when testing Johnson's Baby
- 11 | Powder, would you have attempted to publish your
- 12 research anyway?
- 13 A. Yes.
- 14 Q. If you had found there was no biologic activity
- 15 as a result of the exposure of cells to Johnson's Baby
- 16 | Powder, what would your opinion have been?
- 17 A. My opinion would be at the molecular level,
- 18 | talcum powder exposure does not change the molecular
- 19 level of cells.
- 20 Q. Dr. Saed, if you don't believe you have a
- 21 conflict, why is it you included a disclosure of
- 22 | potential conflicts in the manual you submitted to
- 23 Reproductive Science?
- 24 A. I was criticized by Johnson & Johnson lawyers
- 25 | why I didn't put this. So in the revision when I got

- 1 | the paper, the manuscript, I decided to add it in.
- 2 Q. As you sit here now, do you believe there is a
- 3 | conflict of interest related to the work you did in
- 4 regard to Johnson's Baby Powder?
- 5 A. No.
- 6 Q. What input did plaintiffs' lawyers have into the
- 7 design of the research that you conducted?
- 8 A. None.
- 9 Q. What input did plaintiffs' lawyers have into the
- 10 | methodologies that you employed in conducting your
- 11 research?
- 12 A. None.
- 13 | Q. What input did plaintiffs' lawyers have into the
- 14 | outcome of your research?
- 15 A. None.
- 16 | Q. Did plaintiffs' lawyers have any input into any
- 17 | aspect of the research that you conducted?
- 18 A. The only thing, your Honor, I was asked by them
- 19 is to test -- I initially started with talcum powder
- 20 from Fisher. They asked me if I could test with it
- 21 | Johnson & Johnson Baby Powder. That's the only thing
- 22 | they told me.
- MR. LAPINSKI: Judge Wolfson, do you have any
- 24 | questions for Dr. Saed in regard to the methodologies
- 25 he employed or the reliability of the methodologies he

employed?

1

THE COURT: Not at the moment. I'll wait for

- 3 | the cross-examination, and I know you have redirect.
- 4 Q. Doctor, are you aware of the claims being made
- 5 in this litigation?
- 6 A. Yes.
- 7 Q. What is your understanding of the claims that
- 8 | are being made?
- 9 A. That genital use of Johnson & Johnson Baby
- 10 | Powder subject patients to or individuals, women to
- 11 increased risk of ovarian cancer.
- 12 | Q. Doctor, are your opinions -- strike that.
- Doctor, is the research you conducted and the
- 14 opinions you provided relevant to this litigation?
- 15 A. Yes.
- 16 Q. Why do you think so?
- 17 A. Because showing an effect at the molecule level,
- 18 at the cell level, especially showing the
- 19 transformation process, the gene mutations, the
- 20 uncontrolled cell division, and most importantly,
- 21 showing that if you expose normal ovarian cells to
- 22 | Johnson & Johnson Baby Powder, you can mimic exactly
- 23 | what you see in what we see in ovarian cancer hallmark
- 24 | is significant, and it indicates that the exposure to
- 25 this powder will push the cells towards

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82
    transformation.
1
2
             MR. LAPINSKI: Your Honor, unless you have any
    questions, I'm finished with my questioning.
3
             THE COURT: This is a good time to break and
 4
5
    we'll come back and start the cross. Let's try and do
    about 45 minutes.
6
7
             Thank you.
             THE DEPUTY CLERK: All rise.
8
9
             (The luncheon recess is taken.)
10
            (Continued on the next page.)
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83
                 AFTERNOON SESSION
1
 2
 3
            THE DEPUTY CLERK: All rise.
            THE COURT: Thank you.
 4
 5
 6
    GHASSAN SAED, resumed.
7
8
    CROSS-EXAMINATION
    BY MR. WILLIAMS:
9
         Dr. Saed. Good afternoon, Dr. Saed.
10
    Q.
         Good afternoon.
11
    Α.
12
    Q. Have we met before?
13
    Α.
          No.
14
         My name is Bart Williams, and I represent
15
    Johnson & Johnson, and I have some questions for you
    this afternoon.
16
17
            In front of you you should have two binders,
    No. 1 and No. 2. Those will have exhibit numbers I
18
    will identify.
19
20
            MR. WILLIAMS: For the record, the volumes the
21
    witness has and defense counsel has, we have two
2.2
    different volumes because they are two-sided copies.
23
    The copies for the Court staff and the Court are
    one-sided --
24
25
            THE COURT: Were you warned about that? I do
```

Q. You were first contacted by plaintiffs' counsel,

the Beasley Allen law firm, in the middle of August

21

2.2

23

24

25

Α.

Q.

Α.

Yes.

Yes.

August 2017?

like to read from the first day of Dr. Saed's 1 2 deposition. It is tab 1 in the red binder. It is 3 page 31, line 24 through page 32, line 3. Paragraph. Doctor, do you recall being asked the following 4 question and giving the following answer? 5 "QUESTION: Sure. As of the time you received 6 7 the call from Ms. Thompson, what opinion did you have with regard to talc and ovarian cancer? 8 "ANSWER: That talc is a potential inducer of 9 inflammation and it induces and increases the risk of 10 ovarian cancer." 11 12 Was that the question you were asked and the 13 answer you gave? 14 Your Honor, I mixed up between opinion and 15 conclusion. 16 May you speak into the microphone. Q. 17 When I was contacted by Dr. Thompson, I was Α. already exposed to the media and seeing that the story 18 of ovarian cancer and talcum powder were linked. 19 That's what I was referring to. 20 21 THE COURT: Based on the media you had an 22 opinion? 23 THE WITNESS: No. THE COURT: I didn't understand your answer.

That's what I thought you were just saying. I know

24

you are distinguishing opinion and conclusion? 1 2 THE WITNESS: When I heard the media talking about ovarian cancer, my specialty what I do in our 3 lab is ovarian cancer. So when you hear something 4 that is causing ovarian cancer, it would be in a 5 particular interest to me to test it out. 6 7 THE COURT: That wasn't the question. I'll 8 allow you, Mr. Williams, to ask it again and see if he can listen carefully and answer his question. 9 BY MR. WILLIAMS: 10 Q. My question is this, sir: At the time when you 11 12 were first contacted by plaintiffs' counsel, you had the opinion that talc is a potential inducer of 13 inflammation and it induces increased risks of ovarian 14 15 cancer. Right? 16 THE WITNESS: Your Honor, again, maybe what it 17 says there, maybe that's what I said, but let me explain. I need to explain this. 18 THE COURT: You'll have an opportunity if you 19 want. The question is: Are you answering it today or 20 are you accepting the answer you gave in your 21 22 deposition? That was your testimony. Correct? 23 THE WITNESS: At that time I did not have an

Q. So you are backing off of the testimony that you

24

25

opinion.

```
88
    gave during your deposition. Is that accurate?
1
 2
          Can I explain?
    Α.
 3
          That's okay. I'll move on.
    Q.
            THE COURT: Does he have his deposition in
 4
    front of him?
 5
 6
            MR. LAPINSKI: Can we make sure?
 7
            MR. WILLIAMS: Actually, that's not required
8
    by the rule, but we will do that.
            THE COURT: Since he is accepting what you are
 9
    reading, I want him to have an opportunity to look at
10
    it and see what it says.
11
12
            MR. WILLIAMS: May I approach, your Honor?
            THE COURT: Yes.
13
14
            (Pause.)
15
            THE COURT: Page 31 of your deposition, bottom
16
    of the page on 31.
17
            (Pause.)
18
            THE COURT: Is that what you said?
            THE WITNESS: Yes.
19
20
            THE COURT: I heard what you said. Do you
    still agree with that testimony or are you backing off
21
2.2
    of that testimony? That's his question.
23
            THE WITNESS: I agree with the testimony, yes.
24
          I would like to talk about your opinions
    Q.
25
    regarding causation in this matter.
```

- As we have been discussing already today with
- 2 | plaintiffs' counsel. It is your opinion Johnson's
- 3 | baby powder can cause ovarian cancer in humans.
- 4 | Correct?
- 5 A. Yes.
- 6 Q. It was your objective in preparing your opinion
- 7 | in this case to determine whether the use of talcum
- 8 powder causes ovarian cancer in humans. Correct?
- 9 A. No.
- 10 | Q. It was your objective to determine whether the
- 11 | use of talcum powder poses an increased risk of
- 12 ovarian cancer. True?
- 13 A. My objective was to determine if exposure of
- 14 | cells, normal ovarian cells to talcum powder will
- 15 | induce an inflammatory reaction of the redox balance
- 16 | in the same way that we know it mimics what we see in
- 17 | ovarian cancer. That's my objective.
- 18 Q. The opinion you have given here, both in your
- 19 report and here today, is that Johnson's Baby Powder
- 20 can cause ovarian cancer. Right?
- 21 A. Yes.
- 22 | Q. And you are testifying now that was not your
- 23 | objective?
- 24 | A. Not true. We are mixing up stuff here. I need
- 25 | to explain this. You are mixing up between objective,

- 1 | the objective of my experiments that I did, and then
- 2 | the opinions that I reached based on not only the
- 3 experiments that I did but also on the literature that
- 4 | is published, and also on other people who did the
- 5 same work with talcum powder and cell culture.
- 6 Q. Are you or are you not providing an opinion that
- 7 | talcum powder can cause ovarian cancer in humans?
- 8 A. Yes.
- 9 Q. And you have provided the opinion that it can?
- 10 A. Yes.
- 11 | Q. Your opinion that talcum powder can cause
- 12 ovarian cancer is based upon your in vitro experiments
- 13 | in part. Correct?
- 14 A. Correct.
- 15 | Q. Now, you say talc can result in the development
- 16 of ovarian cancer; true? That's how the phrasing is
- 17 | in your report. Do you remember that?
- 18 A. Yes.
- 19 Q. Do you believe talc exposure can cause other
- 20 gynecological cancers?
- 21 A. Believe this on what, my expertise?
- 22 | Q. Based on anything. Your expertise, what you
- 23 | have studied, the analysis you did in this case.
- 24 | A. I only examined the effect of talcum powder on
- 25 | normal epithelial ovarian cells. I did not test other

- 1 gynecologic cancers.
- 2 Q. Weren't tests done on fallopian cells?
- 3 A. Fallopian is an epithelial that is believed to
- 4 be the source of where ovarian cancer starts. So it's
- 5 relevant to ovarian cancer.
- 6 Q. You do not cite any studies in your expert
- 7 report showing an increase in other gynecological
- 8 | cancers associated with perineal talc use. Correct?
- 9 A. I did not study other gynecologic cancers.
- 10 Q. You did not cite any studies showing an
- 11 | association between talc uses and vagina cancer?
- 12 A. I did not study. This is not my specialty.
- 13 Q. The same with cervical cancer?
- 14 | A. I'm only interested in ovarian cancer. That's
- 15 my lab focus and this is my research.
- 16 Q. The same with uterine cancer. Is that right?
- 17 A. Yes.
- 18 Q. You performed in vitro experiments using
- 19 | Johnson's Baby Powder. Right?
- 20 A. Yes.
- 21 Q. In vitro experiments refers to experiments done
- 22 | with cell lines in a laboratory. In vivo
- 23 experimentation refers to experiments done on animals.
- 24 Right?
- 25 A. And humans.

- 1 Q. You conducted only in vitro experimentations for
- 2 | your report in this case. Right?
- 3 A. Yes.
- 4 Q. You did not try to replicate the results of your
- 5 results that you had received from your in vitro work
- 6 in an in vivo model. Right?
- 7 A. I did not need to.
- 8 Q. My question was whether you did or did not. You
- 9 | did not do any in vivo studies. Correct?
- 10 A. Yes.
- 11 | Q. Can you and I agree that in vivo animal studies
- 12 | are important to determining whether a substance can
- 13 | cause cancer in humans?
- 14 | A. Not necessarily. I disagree.
- 15 | Q. Isn't it true that you believe that an in vitro
- 16 | model can be a good predictor of carcinogenicity in
- 17 | human beings if the same effect is replicated in vivo?
- 18 A. You don't need to. The gold standard to figure
- 19 out a mechanism by which an agent affect induces a
- 20 | specific biological effect at cell level is sufficient
- 21 to draw the conclusion that I did.
- 22 | Q. When have you ever classified a substance as a
- 23 | carcinogen based on the result in an in vitro model?
- 24 A. Like a specific substance you are talking about?
- 25 Q. Yes.

- A. You mean looking at transformation assays? What are you referring to?
 - Q. I'll ask the question again:

If ever, when have you, Dr. Saed, ever classified a substance as a carcinogen based on the results of an in vitro model?

A. Yes, now I understand.

THE WITNESS: Your Honor, all of the work I did for the last 25 years is looking at mechanisms of how ovarian cancer develops, and cause, and these mechanisms are the ones that are replicated when we expose cells to Johnson & Johnson Baby Powder.

I studied the mechanisms that cause ovarian cancer, and we have published extensively in this field, and these mechanisms are replicated when cells were exposed to Johnson & Johnson Baby Powder.

- Q. As you sit here today, Dr. Saed, do you believe an in vitro model is a good predictor to determine whether a substance is a carcinogen or not if the same effect is replicated in vivo? Do you believe that or not today?
- 22 A. If the same effect is replicated in vivo?
- 23 Q. Yes.

24 A. I'm confused. It is two parts. Can we refer to one part at a time.

```
Saled 254 cross/Mr. Williams
                                                            94
          I would like to read from Dr. Saed's testimony
1
 2
    from page 333, tab 1, of the binder, line 5, through
    333, line 12.
 3
 4
            Here is my question to you, Doctor:
 5
            Were you asked the following question, and did
 6
    you give the following answers, on line 5:
 7
            "QUESTION: When have you ever classified a
8
    substance as a carcinogen based on the result in an in
    vitro model?
9
             "ANSWER: In vitro model is a good predictor
10
    to determine whether a substance is carcinogenic or
11
12
    not if the same effect is replicated in vivo.
13
            "QUESTION: You did not replicate your results
    in an in vivo model. Correct?
14
15
            "ANSWER: Not yet."
16
            Were those the questions you were asked and
17
    the answers you gave?
          What page are you reading from, please?
18
    Α.
          333, line 5, through 333, line 12?
19
    Q.
            MR. WILLIAMS: This, your Honor, is the reason
20
    I didn't want to --
21
2.2
            THE COURT: Without looking at the testimony,
23
    do you recall giving that testimony?
24
            THE WITNESS: Yes.
```

THE COURT: We can move on.

- You cannot cite a single instance in which a 1 2 carcinogen has been identified in humans based solely 3 on an in vitro model. True?
 - they induce carcinogenic. They make cells cancer. I can cite many publications that show carcinogenic

No, I can cite the effect of viruses on cells,

- 7 agents can induce and make cells and transform in 8 vitro. I can cite that. There are several studies.
- MR. WILLIAMS: Your Honor, for this we would 9 like to show the videotape of the question and answer, 10 if we could cue up clip No. 8. It appears on page 11 333, line 2, through 333, line 4.

13 (The video was played.)

- "QUESTION: Cite for me an instance when a 14 15 carcinogen has been identified in humans based solely on an in vitro model. 16
- "ANSWER: I can't remember." 17
- BY MR. WILLIAMS: 18
- Now, you have done in vivo studies on animals 19 20 before and you have studied many, many animal models
- 21 over the years. Is that true?
- 2.2 Α. Yes.

4

5

6

- In this litigation, even though you did not 23
- 24 conduct in vivo animal experiments, you still
- 25 concluded Johnson's Baby Powder can cause ovarian

- cancer. Correct? 1
- 2 Α. Yes.
- 3 Did your in vitro experiments determine whether

- talc exposure causes cancer in humans -- not in cell 4
- lines in a petri dish, but in humans? 5
- Could you repeat that. 6 Α.
- 7 Did your in vitro experiments determine whether Q.
- 8 talc exposure causes ovarian cancer in humans, not in
- cell lines in a petri dish, but in humans? Do you 9
- have an answer, sir? 10
- Yes. My work was done in in vitro and cell 11 Α.
- 12 lines. I did not do any in vivo studies in humans.
- 13 Q. One reason you have given us for not using an in
- vivo animal model is that you lacked the time to do 14
- it. Is that correct? 15
- 16 And the money. Α.
- 17 And the other reason is that you lacked the 0.
- money. Is that right? 18
- 19 Α. Yes.
- So time and money are the reasons why those 20
- studies have not yet been done by you? 21
- 2.2 Α. Not the only reason.
- 23 Those are among the reasons. Correct? Q.
- 24 Α. Yes.
- 25 Those are the reasons you explained to us in Q.

- 1 | your deposition?
- 2 A. Among the reasons, yes.
- 3 | Q. Do you remember giving another reason other than
- 4 | time and money?
- 5 A. Yes. The experiments I did in vitro with the
- 6 | cell lines is sufficient to draw my opinion.
- 7 Q. If it is not necessary for purposes of
- 8 determining causation that in vivo studies be done,
- 9 | why is it that you are planning to do biological work
- 10 looking at talc and ovarian cancer if you've already
- 11 | done enough?
- 12 A. If I already did in vitro studies -- I'm sorry.
- 13 I don't understand the question.
- 14 Q. You just testified a moment ago that it is not
- 15 | necessary to do in vivo studies because you already
- 16 | did in vitro studies, did you not?
- 17 A. To get to my opinion, yes.
- 18 Q. If it is not necessary to get to your opinion on
- 19 causation to do in vivo studies, then why use the time
- 20 or money to do those studies?
- 21 A. I didn't do them anyways. I didn't do in vivo
- 22 studies. I did not.
- 23 | Q. I understand you didn't do them. My question is
- 24 | if they are unnecessary because you have already done
- 25 | in vitro studies, why is it that you have testified

- 1 | that it is your plan to do in vivo animal studies?
- 2 A. Our finding, in vitro studies will be enhanced
- 3 | if we can replicate it in a mouse model, an animal
- 4 model.
- 5 | Q. That's kind of my point. You cannot say one way
- 6 or the other, Professor, whether an in vivo animal
- 7 | model will replicate or contradict the results of the
- 8 | in vitro experiments that you have already performed.
- 9 Isn't that right?
- 10 A. That's not true. That's not right. Because the
- 11 | gold standard, using cell lines, when you want to
- 12 delineate to determine the effect of a substance and
- 13 | find out the mechanism of how it creates this effect,
- 14 | you cannot even use an animal model. You have to use
- 15 cell lines. So there is no escape from using cell
- 16 lines. This is the gold standard.
- And my lab, my interest is to determine the
- 18 | mechanism of how this effect is developing the cells,
- 19 pushing the cells to become ovarian cancer. I am not
- 20 | interested in the in vivo effect. My lab is
- 21 interested in determining mechanisms, and to determine
- 22 | mechanisms you do mechanisms and cell culture in
- 23 | vitro. That's my understanding.
- 24 | Q. Just so we're clear, is it your testimony this
- 25 afternoon that you can know the results of an in vivo

- 1 | experiment before you run it?
- 2 A. It is not my testimony. I didn't say that.
- 3 Q. Isn't it true that you are interested in what
- 4 | the in vivo studies would show?
- 5 A. I just said that it will enhance the finding,
- 6 but it will not by itself stand to determine a
- 7 | mechanism, and that's what my interest is.
- 8 Q. Do you believe that it would be contrary to
- 9 | scientific method to purport to know what the results
- 10 of an in vivo study would be before the study is
- 11 | conducted?
- 12 A. I didn't draw any conclusion before the study
- 13 was conducted. I don't know where you got that from.
- 14 Q. My question is different. My question is: Do
- 15 | you believe that it would be proper scientific method
- 16 to purport to know what the result of an in vivo study
- 17 | would be before the in vivo study is even conducted as
- 18 | a matter of methodology?
- 19 A. I'm not objecting to know if someone else did
- 20 it. Yes, that's fine.
- 21 THE COURT: That wasn't his question.
- 22 Q. I'll restate it.
- THE COURT: Okay.
- 24 Q. Do you think it would be proper scientific
- 25 | method for a scientist to say: I know what the result

- 1 of an in vivo study will be because I don't need to do
- 2 | that because I have done an in vitro study?
- 3 A. But I didn't say that.
- 4 Q. I'm asking whether you think that would be
- 5 proper scientific method; do you believe it is proper
- 6 or not?
- 7 A. A scientist is always open to know everything.
- 8 This is my personality.
- 9 | O. I'll move on.
- 10 Let me ask you about some of the animal
- 11 studies that you say you have read in your report.
- 12 | And I would like to direct your attention to the
- 13 | binder that's in front of you. And if you would look
- 14 | in the first binder and look for Exhibit C 17, and
- 15 | that is a copy of your report. I'll direct your
- 16 attention to page 22 of Exhibit C 17.
- MR. LAPINSKI: Your Honor, if I could note for
- 18 | the record, prior to Dr. Saed's January 23rd
- 19 deposition, he had provided a report that had made
- 20 additional notations of research that he had reviewed
- 21 and relied upon. I don't know whether it is going to
- 22 | be at all related to the questions Mr. Williams is
- 23 going to be asking here, but I would like him to have
- 24 | the opportunity also to look at that report.
- THE COURT: Let's see where it goes,

Mr. Williams. 1

2 MR. WILLIAMS: I have no objection to him

- 3 looking at that report.
- BY MR. WILLIAMS: 4
- At the time you gave your initial opinions in 5
- this case -- and I'm directing your attention to page 6
- 7 22 of Exhibit C 17. Do you have that in front of you?
- 8 Α. Yes.
- The numbers I'm referring to in your report are 9
- the numbers that appear at the very top in blue 10
- writing. Do you see that? And it tells you page 22 11
- of 139. 12
- 13 Α. Okay.
- Do you have that page in front of you? 14 Ο.
- 15 Α. Yes.
- 16 You gave the opinion these opinions were made to Q.
- 17 a reasonable degree of scientific certainty and are
- based on your experience, training and expertise. 18
- Correct? 19
- 20 Α. Correct.
- And it says that it is based on a knowledge of 21 Q.
- 2.2 the relevant scientific literature and your previous
- 23 and ongoing research. Right?
- 24 Α. Yes.
- 25 In your reports you have cited literature in Q.

102 support of certain sentences that appear in the 1 2 report. True? 3 Α. Yes. Look at page 11 of your report -- and, again, 4 5 this is referring to the top pages, the page numbering at the top of the page, and it is the last sentence 6 7 that carries over, the last sentence that says, 8 "studies that expose lab animals." Do you see that? 9 Α. Yes. 10 Q. You wrote: 11 "Studies that exposed lab animals, rats, mice, 12 and hamsters to asbestos-free talcum powder in various ways have had mixed results with some showing tumor 13 formation, and others finding only inflammation." 14 15 Do you see that? 16 Α. Yes. 17 You did not review all of the animal studies that look at talc and ovarian cancer when forming your 18 opinions in this case; did you? 19 All of them? 20 Α. 21 Right. Q. 2.2 Α. No. 23 You did cite some studies at the time you gave Q. 24 your opinions. True? 25 Α. Yes.

- 1 Q. And your citation 50 and 51. Do you see that at
- 2 | the end of the sentence?
- 3 A. Yes.
- 4 Q. You expressly cited two studies in your report,
- 5 and those are the only two studies you cite in there
- 6 at the time you rendered your opinions. True?
- 7 MR. LAPINSKI: Your Honor, for the record,
- 8 Dr. Saed's report submitted on January 23rd in these
- 9 specific footnotes, he did add an additional footnote.
- 10 MR. WILLIAMS: I recognize that. I'm trying
- 11 | to go back to the time he originally rendered his
- 12 opinion, your Honor.
- 13 THE COURT: That's fine.
- 14 BY MR. WILLIAMS:
- 15 Q. We can agree those are the only two studies you
- 16 | cited at that time. Correct?
- 17 A. Yes.
- 18 Q. The first of those two studies cited at end note
- 19 | 50 is a 1967 study by Graham entitled, "Ovarian Cancer
- 20 and Asbestos." Do you remember that?
- 21 A. Yes, but I believe that I fixed it.
- 22 | Q. This 1967 Graham study is about asbestos
- 23 exposure, not talc. Right. I think.
- Do you remember that?
- 25 A. Yes. I think I fixed this.

- 1 Q. Let me have you look at Exhibit A 49 in your
- 2 binder. It is a copy of the Graham study. The last
- 3 | sentence of the abstract says: "These observations
- 4 | are compatible with the thesis asbestos is an
- 5 | ideologic factor in ovarian cancer."
- Do you see that?
- 7 A. Yes.
- 8 | Q. Does that refresh your memory the Graham study
- 9 was not a study on animals related to talc but rather
- 10 a study relating to asbestos?
- 11 | A. Your Honor, I have to read the whole manuscript
- 12 | in order to remember. You are quoting one sentence
- 13 | from a whole study.
- 14 | THE COURT: Do you remember the study?
- 15 Obviously, you cited it in your report.
- 16 THE WITNESS: Yes, but I don't remember
- 17 | everything in the study.
- 18 Q. Do you remember the study mentioning the talc
- 19 | anywhere?
- 20 A. I just want to know, your Honor, is this the one
- 21 | that I switched, that I changed?
- 22 Q. We haven't gotten there, sir.
- 23 | A. If it is the wrong citation --
- $24 \mid Q$. This is not the one that's the wrong citation.
- 25 As you sit here now, I will represent to you the word

talc does not appear anywhere in the study, that the study is about asbestos.

As you sit here now testifying to Her Honor, are you able to testify, as you stated in your report, that the Graham and Graham study is a study that exposed lab animals to asbestos free talcum powder and found certain results, can you say that under oath?

8 Α. I have to read the manuscript.

1

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Let's talk about the second study you cited in 9 your report, which is item 51, endnote 51; and this is 10 what I think you were referring to a moment ago, but 11 12 we'll see.

Endnote 51 is a 2004 study by Langseth, entitled, "Ovarian Cancer, Cancer and Occupational Exposure Among Pulp and Paper Employees in Norway."

Do you recall that study?

17 This is what it says in the reference here in my Α. article, yes.

I believe, your Honor, this is the reference where I changed. If I acknowledge it is a mistake and I changed it, why are we going back?

Q. Let's do that now. You were provided a supplemental -- strike that.

Plaintiffs' counsel provided the defense a supplemental list of materials that you reviewed, and

106 one of the items listed was the briefing of the 1 2 parties in this case. 3 Have you read the briefing of the parties in this case as it relates to you? 4 5 A. I read the whole briefing, no. I just read some of it. 6 7 Q. It was listed on a list of items that you had 8 reviewed. Are you saying you did not review the briefs? 9 A. They provided me with a list of items to review, 10 11 yes. 12 Q. Let's take a look at it. If we could call up Saed 501. Plaintiffs' 13 counsel wrote: "Dr. Saed mistakenly cited Langseth 14 2004 instead of Langseth 2008, which is an animal 15 study." 16 Let me ask you this: Did you in fact intend 17 to cite Langseth 2008 in your paper as opposed to 18 Langseth 2004? 19 20 Α. Yes. 21 Let's take a look at Langseth 2008. It is Q. 22 Exhibit A 88 in your first binder. 23 I would direct your attention to page 4, using 24 the numbers at the top of the page at the border, at 25 the top of the page, left-hand column. There is a box

2.2

THE WITNESS: I feel, your Honor -- I feel a problem cutting one sentence from a whole manuscript and asking me about it, if you read the next sentence right after that, it says, "experimental research is needed," and that's what I did.

THE COURT: He's talking about studies that you relied upon. And the question is whether, indeed, these studies supported what you were saying that you — they did this kind of research.

The second sentence says that kind of study is needed. That's not what this study did. He's asking you why you relied upon it for that basis, for that conclusion in your report when it is not what it says.

- A. I relied on it as evidence there is an effect that needs to be further experienced.
- Q. Let's go back and clear that up.

If we could pull up C 17, your MDL report, and the sentence that talks about what you actually said.

You wrote, this is page 12, carrying over to 13 of Exhibit C 17. You wrote:

"Studies that exposed lab animals, rats, mice, and hamsters to asbestos-free talcum powder in various ways have had mixed results with some showing tumor formation and others finding only inflammation ."

That's what you wrote. Correct?

- 1 A. Yes.
- 2 Q. Langseth 2008 did not involve laboratory animal
- 3 studies. Can we agree on that?
- 4 A. I have to read the whole -- I don't know.
- 5 Q. You can't say one way or the other as you sit
- 6 there. Right?
- 7 A. I have to read the manuscript to be able to
- 8 remember what I said.
- 9 Q. Now, counsel, when he was objecting a moment
- 10 ago, referenced another item that you read that
- 11 | supported this sentence. Do you remember that?
- 12 | Counsel objected and he said there was another study
- 13 added that you read.
- 14 A. Keep going.
- 15 Q. Do you remember what the other study is that
- 16 | supposedly supports this sentence that appears in your
- 17 report at pages 12 and 13?
- 18 A. I referenced in the new report the independent
- 19 study.
- 20 Q. Is the independent 1993 study and the two that
- 21 | you've cited on page 12 and 13, are those the only
- 22 | studies upon which you are relying for the proposition
- 23 I read three times on pages 12 and 13?
- 24 | A. As far as animal studies?
- 25 Q. As far as the proposition that you cite on pages

110 12 and 13? 1 2 Using the effect on animals in vivo? Α. 3 Q. Yes. 4 Α. Yes. Are you aware of animal studies that actually 5 Q. have looked at talc exposure in the ovaries? 6 7 I am aware of a study that injected talc into Α. 8 the perineal cavity of an animal and looked at the 9 severe inflammation of that, yes. Is that the 2009 study? 10 Q. 11 I can't remember dates. Α. 12 THE COURT: He's asking if you recognize the author's name of the study? 13 THE WITNESS: No. 14 15 Let me ask you to look in your book at Exhibit A 85? 16 MR. WILLIAMS: For the record, Exhibit A 85 is 17 a document entitled, "Does long-term talc exposure 18 have a carcinogenic effect on the female genital 19 system of rats, an experimental pilot study?" 20 21 Have you read this study, sir? Q. 2.2 Α. No. Let me direct your attention to page 2 -- which 23 Q. 24 is the page we are on, the first page, the abstract, 25 and in the right-hand column it says:

- 111 "The experimental animals were allocated into 1 2 four groups having seven rats each. Groups 3 and 4 3 received intravaginal or perineal talc application respectively. Talc was applied for three months on a 4 daily basis." 5 6 Did I read that right? 7 Yes. Α.
- 8 Let me direct your attention to the bottom of postmenopausal column where it says, "Conclusions."
- Do you see that? 10
- Α. 11 Yes.

- 12 It says, "Talc has unfavorable effects on the
- 13 female genital system. However, this effect is in the
- 14 form of foreign body reaction and infection rather
- than being neoplastic." Did I read it correctly? 15
- 16 Α. Yes.
- You had not read this study at the time you 17
- rendered your opinions in this case. Correct? 18
- I don't remember really. 19
- Did you review a paper called, "The Effects of 20
- Talc on the Rat Ovary," written in 1984 called 21
- Hamilton? 2.2
- 23 Α. No.
- 24 Let me have you look at Exhibit A 53. Q.
- 25 MR. WILLIAMS: For the record, your Honor,

- 1 | Exhibit A 53 is Hamilton 1984, "The Effects of Talc on
- 2 | the Rat Ovary."
- 3 Q. Do you see it says under the summary, the first
- 4 line: "Exposure of rat ovaries to talc was a column
- 5 | published by intrabursal injection." Do you see that?
- 6 A. Yes.
- 7 | Q. "Intrabursal" here means the scientists here
- 8 | injected the ovaries of the rats with talcum powder.
- 9 | Is that what that means?
- 10 A. Yes.
- 11 | Q. Now, if you look at page 4 of Exhibit A 53 in
- 12 | the right-hand column above the photograph, it says:
- "No evidence of cellular atypia or of mitotic
- 14 | activity was seen in the nonpapillary areas of the
- 15 | surface epithelium of the injected ovaries and in no
- 16 ovary was there any evidence of frank neoplasia." Did
- 17 | I read that right?
- 18 A. Yes.
- 19 Q. Neoplasia refers to the formation of tumors;
- 20 does it not?
- 21 A. It does.
- 22 | Q. In this study the rats were injected in their
- 23 | ovaries with talcum powder, there was no evidence of
- 24 | neoplasia was there?
- 25 A. That's what they think.

- 1 Q. As you sit here now, can you cite for the Court
- 2 a study that injected rats or other animals in their
- 3 ovaries with talcum powder where those ovaries showed
- 4 | evidence of neoplasia?
- 5 THE WITNESS: Your Honor, the paper where they
- 6 | injected talc in the cavity and found inflammation
- 7 other than that I don't have.
- 8 Q. There is a big difference between inflammation
- 9 on the one hand and neoplasia on the other. Can we
- 10 | agree on that?
- 11 A. No.
- 12 Q. As far as you are concerned, neoplasia and
- 13 | inflammation are one and the same?
- 14 A. I didn't say that.
- 15 Q. Then let me go back to my original question.
- 16 We can agree there is a big difference,
- 17 Doctor, between inflammation on the one hand and
- 18 | neoplasia on the other; can we not?
- 19 A. I need to explain this.
- 20 | Q. Go ahead.
- 21 A. What I'm saying is inflammation -- we have two
- 22 | types of inflammation. If it is acute inflammation,
- 23 | that has been shown it is acute. It goes for a while.
- 24 | It comes back. That is not dangerous. The dangerous
- 25 | type of inflammation, that's what I'm talking about,

- 1 is chronic inflammation where it persists for a long
- 2 | period. That is linked in -- several studies to cause
- 3 cancer, yes.
- 4 Q. My question was different. My question was
- 5 | whether the study -- that you can't remember the name
- 6 of, but that you are referring to that and talked
- 7 about placing talc in, I believe, the peritoneal
- 8 | cavity, whether that study showed any actual neoplasia
- 9 with respect to ovarian cells?
- 10 A. It showed severe inflammation because they did
- 11 | not expose it for a long period.
- 12 Q. It did not show neoplasia?
- 13 A. I don't remember. They are talking about
- 14 inflammation.
- 15 Q. Let's go back to Hamilton for one second. It
- 16 | is Exhibit A 53, page 4. I read to you that paragraph
- 17 that ends with the word "neoplasia," but it goes on to
- 18 say in the next paragraph: "Foreign body granulomas
- 19 | without any surrounding inflammation were seen in five
- 20 of the injected ovaries, usually cortical areas, and
- 21 similar lesions were not uncommonly noted in the supra
- 22 | capsular fat and in the connective tissue matrix of
- 23 | the capsule."
- 24 Did I read that right?
- 25 A. Yes.

- 1 Q. So the Hamilton study found granulomas.
- 2 | Correct?
- 3 A. That's what you read, yes.
- 4 Q. Granulomas can result from pricking your finger
- 5 | with a splinter, if there was any kind of foreign
- 6 | body, separate from talc. You can have a granuloma.
- 7 A. I don't know. I do know that this is a
- 8 | condition study. So based on the doses that he used,
- 9 | based on their conditions, this is their finding. I
- 10 | may agree with it. I may disagree with it.
- 11 My point I'm trying to tell you here,
- 12 | inflammation -- chronic inflammation is linked, your
- 13 Honor, to the development, at the causation of ovarian
- 14 cancer. Period.
- 15 Q. That's the way you want to leave it?
- 16 A. That's how I understand it. There are many
- 17 researchers that say this and this. That's okay. But
- 18 | we are talking about laboratory-evidence based here.
- 19 Q. Let me focus you now on that proposal that was
- 20 | shown to you by plaintiffs' counsel. It is the
- 21 proposal that set forth your three aims. Do you
- 22 recall that document?
- 23 | A. I do.
- 24 Q. You told us earlier you were not able to conduct
- 25 | an in vivo animal experiment with talc because you did

- not have the money to do so. Correct? 1
- 2 Α. Correct.
- 3 For your in vitro experiments you created what
- you called a budget document entitled, "The Role of 4
- Talc Powder Exposure in Ovarian Cancer, a Mechanistic 5
- Approach." Right? 6
- 7 Yes. Α.
- 8 Q. You prepared that document in September 2017?
- 9 Α. Yes.
- That was about one month after you were first 10 Q.
- contacted by the plaintiffs' attorneys, which occurred 11
- 12 in the middle of August 2017. We established that
- 13 earlier. Right?
- 14 Α. Yes.
- 15 You created the document before you started
- 16 doing any work in this case?
- Not true. Let me explain this. 17 Α.
- Hold on. You said "not true"? 18 Q.
- You did not start your work on this case until 19
- the end of September or October of 2017. True? 20
- 21 May I -- let me see. When is the first time we Α.
- 22 started working.
- Let me see if I can remind you with your 23
- 24 testimony. Take a look at the red binder, page 23 of
- 25 tab 1.

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117
            THE COURT: Dr. Saed, he's directing you to a
1
 2
    document.
          Page 23 of tab 1. That's your testimony, the
 3
    first day of your deposition. That was January 23rd,
 4
 5
    2019. I'll direct your attention to page 23, line 24,
    through page 24, line 5:
 6
 7
            "QUESTION: When did that something start?
    When is the first time that you spent any time on this
8
9
    matter on behalf of Beasley Allen?
            "ANSWER: So I started October maybe 1st of
10
    October, maybe before that. I can't remember the
11
12
    exact date.
13
            "QUESTION: What is your best estimate?
            "ANSWER: I would say end of September."
14
15
            That's what you testified to during your
16
    deposition. Correct?
17
    Α.
          Yes.
          Now, no one asked you to prepare the document
18
    that is the proposal document. Right?
19
20
    Α.
          Yes.
21
          You prepared that document with care?
    Q.
          I don't understand what that means?
2.2
    Α.
          Were you careful in analyzing the way you were
23
24
    going to go about achieving the aims set forth in the
    document?
25
```

1 Α. Yes.

2 After you completed that document you provided Q.

- 3 it to the plaintiffs' lawyers who had not asked you
- 4 for it. Right?
- I can't remember. 5 Α.
- You can't remember if they asked you for it or 6 Q.
- 7 you can't remember if you gave it to them?
- 8 Α. I remember I gave it to them. I don't remember
- if they asked me or not. 9
- Let's look at that document. We marked it as 10
- B-25. It should be in your first binder. 11
- 12 Let's look at page 2, which is the page marked
- 13 at the top. It says, quote:
- "The role of talc powder exposure in ovarian 14
- 15 cancer, the mechanistic approach."
- Right? 16
- 17 Α. Yes.
- The paragraph that follows describes your 18
- laboratory's research area and some of its 19
- accomplishments. Do you see that? 20
- 21 Α. Yes.
- 22 The next paragraph on page 2 describes prior
- research on ovarian cancer including some of the 23
- 24 research your own lab has done -- and I'll refer you
- 25 to the line that has been highlighted, which was

- 1 | underlined in your original report. Right?
- 2 A. Yes.
- 3 Q. And then at the bottom, the last sentence of
- 4 | this paragraph on page 2 says, in italics, and
- 5 | underlined:
- 6 "Here our objective is to determine whether
- 7 | talc can induce such mutations in the key redox
- 8 | enzymes contributing to the oncogenic phenotype."
- 9 Did I read that right?
- 10 A. Yes.
- 11 | Q. Let's turn to page 3, the first paragraph.
- 12 Let me ask you this question, is it true as of
- 13 | the time you wrote your proposal, you believed that
- 14 | the direct link and precise mechanism between talc and
- 15 ovarian cancer had not been figured out?
- 16 A. I didn't do any work with talc before that, yes.
- 17 Q. At the time you wrote your proposal, you did not
- 18 believe that a direct link and precise mechanism had
- 19 been developed suggesting an association between talc
- 20 use and ovarian cancer. Right?
- 21 A. Yes. Not enough evidence.
- 22 Q. Say that again.
- 23 | A. I believe there was not enough evidence. Maybe
- 24 | we needed to do experiments.
- 25 | Q. It wasn't until your experiments that you

- believe that link was found? 1
- 2 Α. Yes.
- 3 Do you agree that one of the fundamental rules

- for performing scientific analysis is that it should 4
- be performed in a forward-looking and unbiased manner? 5
- 6 Α. Yes.
- 7 Should a scientist determine her or his Q.
- 8 conclusion before she has done her tests?
- 9 Α. No.
- Let's look at your third aim -- I want to start 10 Q.
- with that one first, if I may. It is on page 4 of the 11
- 12 document. Do you see that?
- 13 Α. Yes.
- Aim No. 3 was "Exposure to talc results in 14
- 15 neoplastic transformation of normal ovarian surface
- epithelial cells." 16
- 17 You wrote that. Right?
- Α. Yes. 18
- That was a declarative sentence. Right? 19 Q.
- 20 No. That's a hypothesis-driven aim. Α.
- 21 This is your hypothesis? Q.
- 2.2 Α. Correct.
- The term "neoplastic transformation" refers to 23
- 24 normal ovarian cells changing into cancer cells.
- 25 Right?

121 Yes. 1 Α. 2 In the next sentence of Aim No. 3 you write: Q. 3 "To accomplish this aim," comma, and then you 4 go on. Right? 5 Yes. Α. What you were doing here was saying, I have a 6 Q. 7 hypothesis and here is how I want to go about testing 8 that hypothesis. Is that fair? 9 Α. Yes. The way that you said you would go about testing 10 Q. the hypothesis was that you would "assess the ability 11 of talc exposure to cause neoplastic changes in normal 12 ovarian surface epithelial cells utilizing a 13 neoplastic transformation assay as previously 14 15 described." Did I read that right? 16 Α. Yes. 17 You never performed a neoplastic transformation assay as described in Aim 3. Right? 18 19 Right. Α. 20 Let's go to the bottom of Aim 3. Do you see the sentence that you had in bold and italics -- we've 21 22 highlighted it -- you wrote and emphasized: 23 "We expect that exposure of normal ovarian

24 surface epithelial cells to talc will result in
25 neoplastic transformation of these cells over time

122 which is critical in establishing a cause and effect 1 2 relationship." 3 You wrote that; right? Yes. 4 Α. 5 Q. As a matter of fact, you never performed tests 6 to look for neoplastic changes in the cells. Correct? 7 Not correct. Α. 8 Q. Have you ever done any test to look for 9 neoplastic changes in cells directly? 10 Α. Yes. Let me have you look at your red binder, and 11 Q. 12 I'll direct you and the Court and counsel to page 465 13 of your first deposition, lines 2 through 4 -actually, it is the second tab, the second day of your 14 15 deposition, Doctor, page 465, lines 2 through 4. were asked the following question and gave the 16 17 following answer: 18 "QUESTION: Have you ever done any test to look for neoplastic changes in cells directly? 19 20 "ANSWER: No." 21 That was your answer to the question during 2.2 your deposition on February 14th, 2019. Correct? Yes. But let me explain that. 23 Α. 24 That's all right, Doctor. You'll do that

25 through plaintiffs' counsel in a moment, if that's

1 okay. I would like to move on.

Your aim was to describe to the reader how you would go about testing your hypothesis. That's why

- 4 | you wrote Aim No. 3. Right?
- 5 A. To the reader. That's for me. That's for my
- 6 lab.
- 7 Q. Your goal as a lab was to do some testing to try
- 8 to figure out whether there was a cause and effect
- 9 relationship between talcum powder use and ovarian
- 10 | cancer. Right?
- 11 | A. I cannot answer yes or no. I have to explain.
- 12 Your Honor, may I?
- 13 THE COURT: Go ahead.
- 14 A. I proposed three specific aims, not one, three
- 15 | specific aims: Aim 1 to look at the redox balance
- 16 change and look at genetic mutation. Aim 2, looking
- 17 at inflammation; Aim 3, looking at neoplastic
- 18 transformation. We started one by one. We got
- 19 | convincing evidence from Aim 1 and 2; and when we did
- 20 | the proliferation and apoptosis, which are strong
- 21 | indicators of cell transformation, we were happy with
- 22 that finding. We didn't need to do a new
- 23 transformation assay.
- 24 | Q. Did you or did you not write on Aim 3 that
- 25 | neoplastic transformation of the cells over time would

```
124
    be critical in establishing a cause and effect
1
 2
    relationship?
 3
    Α.
         I did.
         Let me turn to Aim 1. That is on page 3.
 4
    Q.
 5
    states:
            "Determine the effect of talc on the redox
 6
7
    balance on normal ovarian surface epithelial and
    ovarian cancer cells."
8
 9
            Right?
10
    Α.
          Yes.
          Like you did for Aim No. 3, the next sentence
11
    Q.
12
    begins with:
            "To accomplish this aim," -- a then you set
13
    forth how to accomplish it. Is that fair?
14
15
    Α.
          Yes.
          You go on in this paragraph to discuss specific
16
    Q.
17
    tests that would accomplish the goal set out in aim
    No. 1. Right?
18
19
    Α.
         Yes.
20
          For example, you refer to measuring the
    "activity and expression of select oxidants and
21
2.2
    antioxidants in cell culture lysate from primary
    cultures of ovarian surface epithelial cells."
23
24
            Did you write that?
25
    Α.
         Yes.
```

- Q. You did not actually perform all of the tests that are described in Aim 1; did you?
 - A. No, I did not.

- 4 Q. Can we agree that you did not set forth in aim
- 5 No. 1 that you were going to do one of the tests
- 6 | identified, but that you may not do the others?
- 7 THE WITNESS: Your Honor, these are all the
- 8 | tests that we have established in the laboratory. We
- 9 did six markers out of the list that we proposed to do
- 10 here. Do we need to do all of them? No. We don't
- 11 | need to do all of them. From our experience, working
- 12 | with this for the last 25 plus years, we already
- 13 | identified and published markers that play a key role
- 14 | in altering the redox balance. That's what we
- 15 | reported in our manuscript.
- 16 Q. My question was different. My question was:
- 17 | You did not describe in the portion of Aim No. 1 that
- 18 | speaks about how you were going to accomplish your aim
- 19 | that you were going to try one or maybe two or maybe
- 20 | three of the different types of tests. You just
- 21 listed the things that you felt should be done in
- 22 order to test the hypothesis. Right?
- 23 | A. I listed the tests that we had available in our
- 24 | lab to go about and accomplish this aim. Does that
- 25 mean we have to do all the tests? The answer is no.

- 1 Q. And the reason you did not do all the tests was
- 2 money. Right?
- 3 A. In this case, part of it, yes.
- 4 Q. Let's go to Aim No. 2. That one is on page 3.
- 5 A. For the record, I believe, your Honor, we did
- 6 enough to prove the point.
- 7 Q. Let's go to Aim 2. Aim 2 said:
- 8 "Determine whether exposure to talc can induce
- 9 point mutations that correspond to known SNPs in key
- 10 oxidant and antioxidant enzymes as well as BRCA
- 11 one/two in normal ovarian surface epithelial and
- 12 | ovarian cancer cells."
- Did I read that right?
- 14 A. Yes.
- 15 Q. "SNP" refers to a single nucleotide
- 16 | polymorphism. Right?
- 17 A. Yes.
- 18 Q. That is a mutation?
- 19 A. Yes. DNA.
- 20 Q. Sometimes referred to as a copying error?
- 21 A. I'm not sure about that.
- 22 | Q. In Aim No. 2 you list a number of SNPs that you
- 23 | say you had previously analyzed in ovarian cancer
- 24 | cells and patient DNA. Right?
- 25 A. Yes.

```
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          And so on the carry-over paragraph at the top of
1
 2
    page 4 you wrote:
 3
             "We have previously analyzed the following
    SNPs in EOC cells and patient DNA."
 4
 5
            And then you give a listing. Right?
 6
    Α.
          Yes.
7
          What I want to do is I want to set out a list of
    Q.
8
    the various SNPs that you had previously analyzed as
9
    you indicated here. Okay?
10
    Α.
          Okay.
          I'm just going to refer to them with the letters
11
    Q.
12
    that are within in parenthesis. The first is CYBA?
13
    Α.
         Yes.
          The second is MnSOD?
14
    Ο.
15
    Α.
          Yes.
          The next is NOS2.
16
    Q.
17
            Next is GPX1. Is that right, sir?
          Yes.
18
    Α.
          Next is CAT?
19
    Q.
20
    Α.
          Yes.
21
          Next is MPO?
    Q.
2.2
    Α.
          Yes.
          And, finally, GSR?
23
    Q.
24
    Α.
          Yes.
25
          You identified seven different SNPs that you had
    Q.
```

previously analyzed. Right? 1

- 2 Α. Yes.
- 3 And you had published findings in a
- peer-reviewed paper concerning those SNPs; true? 4
- Yes, some of them. 5 Α.
- 6 Let me point you to one of them. You Q.
- 7 co-authored in 2015 a paper entitled, "A Single
- 8 Nucleotide Polymorphism in Catalase is Strongly
- Associated With Ovarian Cancer Survival." Do you 9
- remember that? 10
- Yes, I do. 11 Α.
- 12 Let me have you refer in the second notebook now
- -- it's the first time we have done that -- to Saed 13
- Exhibit 502. Let me direct you to the third page of 14
- 15 that document looking at the bottom -- do you see
- 16 where it says three of 12 at the bottom of the page?
- 17 Α. Yes.
- The seven selected SNPs that were reviewed by 18
- you and your colleagues in this particular study are 19
- shown at the top of page 3 on a chart over at the 20
- 21 left. Right?
- 2.2 Α. Yes.
- And it turns out those are the seven SNPs that 23
- 24 you analyzed in connection with your work in this
- 25 case. Correct?

```
129
         For the cell culture, yes.
1
 2
            MR. WILLIAMS: For the record, let's point
 3
    that out.
    Q. The first one listed in Table 1 on that page 3
 4
    is CAT?
 5
         Catalase.
    A.
 6
 7
    Q. CYBA is next?
8
    Α.
         Yes.
         And GPX1?
9
    Ο.
    A. Yes.
10
         And GSR?
11
    Q.
12
    Α.
         Yes.
         MnSOD?
13
    Q.
14
    Α.
         Yes.
15
    Q.
         MPO?
16
    Α.
         Yes.
17
    0.
         And NOS2. Correct?
18
          Yes.
    Α.
          Those are the same seven that you reviewed for
19
    Q.
    purposes of this matter. Right?
20
21
         Yes, but I need to, your Honor, clarify this.
    Α.
            This study is done in patients with ovarian
2.2
    cancer. There is no inflammation whatsoever if those
23
    patients were exposed to talc powder or not. This is
24
    just DNA from patients that has nothing to do -- what
25
```

- 1 we did here, analyzing these SNPs in cells, treated
- 2 | with Johnson & Johnson Baby Powder, that's the big
- 3 difference here. I just want to note that.
- 4 Q. Let me ask you this: Do you remember one way or
- 5 | the other, Dr. Saed, whether of the seven selected
- 6 | SNPs that are listed in this study, there was an
- 7 association with ovarian cancer risk? Do you remember
- 8 one way or the other?
- 9 A. I remember, yes. I remember there was an MPO
- 10 | SNP that is not the one listed here is associated with
- 11 | ovarian cancer, yes. What I'm trying to explain here
- 12 | is that there are more, your Honor; there are more
- 13 than one reported SNP on the same gene, more than one.
- 14 | If you pick one and you don't find an effect, that
- 15 doesn't mean there is no association. That is very
- 16 clear.
- 17 Q. If we can go back to the abstract. In the
- 18 | abstract, the conclusion that you reached, you and
- 19 | your colleagues, was of the seven selected SNPs
- 20 studied, no association with ovarian cancer risk
- 21 | Pearson, CHI-square was found?
- 22 The conclusion of this study was for the same
- 23 | seven SNPs listed, there was no association with
- 24 ovarian cancer risk. Right?
- 25 A. Those specific SNPs with those genes -- and

S104291Cross/Mr. Williams

these are patients, not cell lines exposed with talcum 1

- 2 powder.
- 3 0. Yes or no?
- Α. Yes. 4
- 5 Was there an association that was found between Q.
- the SNPs listed on the board right now and ovarian 6
- 7 cancer?
- There was an association of catalase SNP with 8
- 9 survival of patients with ovarian cancer.
- Let's go back and read the next sentence. It 10
- 11 says:
- 12 "However, a catalase SNP was identified as a
- 13 predictor of ovarian cancer survival by the Cox
- Regression Model." Did I read that right? 14
- 15 That's what I just said.
- 16 What that is saying, if someone already had Q.
- 17 ovarian cancer, there was an association with one of
- the SNPs with ovarian cancer survival. Right? 18
- 19 Α. Not necessarily.
- Well, is it true or not true that the seven SNPs 20 Ο.
- that you and your colleagues studied found no 21
- association with ovarian cancer risk as indicated in 2.2
- the abstract? 23
- 24 Α. Yes.
- 25 Q. That was true?

- 1 A. Yes. But I have to say something else.
- 2 Q. There is no question pending. You will get a
- 3 chance with other counsel. Thank you.
- Do you remember, Dr. Saed, when we were
- 5 | talking about Aim No. 2 of your proposal, you had
- 6 stated that you were going to look at certain key
- 7 oxidant and antioxidant enzymes as well as BRCA 1 and
- 8 2? Do you remember that?
- 9 A. Yes, I do.
- 10 Q. BRCA 1 and 2 are human tumor suppressor genes.
- 11 | Right?
- 12 A. Yes.
- 13 Q. It is well known that mutations to the BRCA 1
- 14 | and 2 genes can result in an increased risk of ovarian
- 15 | cancer. Right?
- 16 A. Yes. Associated with. That's different.
- 17 Q. That is why in your Aim No. 2 you proposed to
- 18 | analyze SNPs for BRCA 1 and 2. Right?
- 19 A. When I did this, I wanted to do the ones that
- 20 | are relevant to redox balance. After we run the one
- 21 | with redox balance, if the data shows there is a need
- 22 | for us to differentiate or study if there is a
- 23 differential effect between patients with BRCA 1
- 24 | mutation positive or negative. That's the idea why I
- 25 | put it there. I didn't necessarily want to do them.

- 1 | I wanted to do them if and when I collect enough data
- 2 to try to segregate and see if the response that we
- 3 | see the association response is linked to patients
- 4 | with BRCA 1 positive versus BRCA 1 negative.
- 5 Q. In your Aim No. 2, did you say anything like
- 6 | what you just said was your intention?
- 7 A. No.
- 8 | Q. Let's look at Aim No. 2. B 25 is the exhibit.
- 9 And if we could pull up page 4. What you wrote was:
- "Due to the known strong association between
- 11 | BRCA 1 and 2 and ovarian cancer, we propose to analyze
- 12 | the following SNPs" -- and then you give a long list.
- 13 | Correct?
- 14 A. Where did you get this from?
- 15 Q. It is up on your monitor about seven lines down.
- 16 | What you wrote in your proposal -- that's what you
- 17 | wrote. Right?
- 18 | A. Yes.
- 19 Q. And you didn't write anything about how you were
- 20 going to do the tests on the other SNPs, and you had
- 21 only gone into BRCA 1 and BRCA 2 if something
- 22 | happened. None of that is in here. Right?
- 23 A. I don't have to write it in here. This is a
- 24 proposal for me, for my lab.
- 25 Q. For the record, so it is clear, at the time you

- 1 | wrote your proposal, you knew there was an association
- 2 between BRCA 1 and BRCA 2 and ovarian cancer. Right?
- 3 A. Yes.
- 4 Q. You had done research yourself concerning the
- 5 | seven SNPs that were listed on the board a moment ago
- 6 and had come to a conclusion with your colleagues that
- 7 | there was no association between those SNPs and
- 8 ovarian cancer. Right?
- 9 A. Not right. Completely not right -- I mean,
- 10 partially not right. I'm sorry.
- 11 I'm surprised, your Honor, how you pick one --
- 12 THE COURT: Don't give your view of that.
- 13 A. There is another study that linked these same
- 14 | SNPs to chemo-resistant ovarian cancer.
- 15 Q. What you're saying now is, there was a study
- 16 | that analyzed the seven SNPs that showed no
- 17 | association with ovarian cancer and another one that
- 18 | found association with ovarian cancer. Is that what
- 19 | you are saying?
- 20 A. No. What I'm saying is these studies are
- 21 performed in DNA from patients. The other studies
- 22 that we did were DNA from ovarian cancer cells
- 23 developed to become chemo-resistant to chemotherapy.
- 24 When we developed them, we derived them, we made them
- 25 resistant to chemotherapy. They acquired these SNPs

- 1 | in the key enzymes and they correlated with
- 2 chemo-resistance. That we published previously.
- 3 Q. Are you saying the conclusions that were drawn
- 4 | in your 2015 study that we had up on the board a
- 5 | moment ago have been disproven?
- 6 A. How? What study? They are different studies.
- 7 You cannot compare. This is DNA from patients and
- 8 | these are specific in vitro studies with cells. I
- 9 don't know how you can compare that.
- 10 Q. Are you stating that the 2015 study that you and
- 11 | your colleagues corrected concerning the seven SNPs we
- 12 | had up on the board where one of the conclusions
- 13 reached was there was no association between those
- 14 | seven SNPs and ovarian cancer, are you now saying that
- 15 | conclusion has been disproven since 2015?
- 16 A. No.
- 17 | Q. Let me change subjects and ask you about your
- 18 manuscripts quickly.
- 19 You submitted your manuscript to a journal
- 20 | called Reproductive Sciences in January of 2019. Do
- 21 | you remember that?
- 22 A. Yes.
- 23 | Q. You spent approximately 60 to 70 hours preparing
- 24 | that manuscript. True?
- 25 A. Yes.

- 1 Q. You billed your time spent preparing the
- 2 | manuscript to the plaintiffs' lawyers at Beasley
- 3 Allen. Correct?
- 4 A. Yes.
- 5 Q. You charged plaintiffs' counsel \$600 an hour for
- 6 your work on this matter. Right?
- 7 A. The manuscript and the expert report, yes.
- 8 Q. You did not tell the Journal of Reproductive
- 9 | Sciences when you originally submitted to them that
- 10 | the lawyers had paid you by the hour to write the
- 11 | manuscript that you submitted. Correct?
- 12 A. I didn't need to.
- 13 | Q. How many other papers listed on your CV did the
- 14 | lawyers pay for your time to write?
- 15 A. Zero.
- 16 | Q. Did the plaintiffs' lawyers receive the
- 17 | manuscript before you submitted it to the Journal of
- 18 | Reproductive Sciences?
- 19 A. No.
- 20 Q. Now, unlike your expert report in this case, the
- 21 | manuscript that you submitted for publication, the
- 22 | peer-reviewed article for the Journal of Reproductive
- 23 | Sciences does not say that talc can cause ovarian
- 24 | cancer. Correct?
- 25 A. In what manuscript? The Reproductive Science

S104297Cross/Mr. Williams 137 1 one? 2 Q. Correct. 3 What does it say? Α. I'm asking you this question: In the report you 4 set forth for Her Honor in this case --5 6 Α. Yes. 7 -- you rendered the opinion talc can cause 8 ovarian cancer, correct? You say it flat out. True? 9 Α. Yes. In the manuscript that you wrote and submitted 10 Q. to the Journal of Reproductive Sciences, you did not 11 12 come flat out and say talc can cause ovarian cancer; did you? 13 14 A. Yes. In the manuscript, your Honor, you provide 15 a conclusion, not an opinion. In the report, I provided a conclusion and an opinion. 16 17 Q. Is it your testimony that scientists, when they submit studies, never will set forth an opinion on 18 causation? 19 Yes, sometimes they do. 20 You did not set forth an opinion on causation 21 Q. 22 for the Journal of Reproductive Sciences; true or not 23 true? 24 A. I have to remember the exact words that I said

in the manuscript. I can't remember. I have to read

- 1 | the language, your Honor, that I said.
- Q. Let me refer you to your testimony. This is on page 244.
- MR. WILLIAMS: It is tab 1, your Honor, in the red binder, page 244, line 18, through 245, line 12.
- Q. You were asked the following questions and gave the following answers:
- 8 "QUESTION: Even in your manuscript you don't
 9 include the opinion that talcum powder use causes
 10 ovarian cancer. Correct?
- "ANSWER: You cannot include opinions in manuscripts.
 - "QUESTION: That's not my question. My question is that your manuscript does not include your opinion that talcum powder use causes ovarian cancer.

 Correct?
- "ANSWER: I answered you."

14

15

16

18

19

20

- So let me ask you this: Did you or did you not provide a conclusion in the manuscript that you provided to the Journal of Reproductive Sciences that talc can cause ovarian cancer?
- 22 A. I did provide a conclusion that based on my data 23 there will be an increased risk of developing ovarian 24 cancer, yes. I did not provide an opinion.
- 25 Q. It will speak for itself.

```
139
            The Journal of Reproductive Sciences was not
1
 2
    the first journal to receive your manuscript. Right?
 3
    Α.
          Yes.
          The first choice or the first journal that you
 4
    Q.
    submitted it to was Gynecologic Oncology. Right?
 5
 6
    Α.
          Yes.
 7
          I want to ask you about the response you
    received. You were asked about this on DIRECT
8
 9
    EXAMINATION. Let me direct you to B-23, page 3.
            I want to direct your attention to the
10
    important limitations that were set forth there by
11
12
    Reviewer No. 1.
            The first limitation reads:
13
             "The significance of the study would be
14
15
    greatly enhanced if the mouse model corroborated the
    cell line findings."
16
17
    A. Yes.
          That's an in vivo study?
18
    Q.
19
    Α.
          Right.
20
          The next sentence indicates the expert believes
    Ο.
    your cell line studies were not convincing,
21
22
    sufficiently convincing.
```

The third limitation, "The first bulleted

Do you see that?

23

24

25

Α.

Q.

Yes.

```
140
    highlight says, oxidative stress is a key mechanism to
1
 2
    the initiation and progression of ovarian cancer is
    not supported by this investigation and should be
 3
    omitted."
 4
 5
            Do you see that?
 6
    Α.
          I do.
 7
          Now, you said earlier today that you had
8
    previously submitted a paper that had language not
    exactly like that but to that effect. Do you remember
 9
    that?
10
    Α.
          The review article?
11
12
          The review article. Right?
    Q.
13
    Α.
          Yes.
14
          Now, you understood when the reviewer was
15
    reviewing your manuscript for Gynecologic Oncology the
16
    reviewer was not talking about another paper. Right?
17
    Α.
         Yes.
          The reviewer was talking about your paper we are
18
    discussing here. Correct?
19
          Correct.
20
    Α.
          And it was this paper the reviewer was saying
21
    Q.
22
    did not support that conclusion. True? Did you
23
    understand that to be what they were saying?
24
          Yes, I understand, but may I --
    Α.
25
          Did you understand at the time the reviewer
    Q.
```

- 1 responded that he or she was saying this paper does
- 2 | not support that proposition?
- 3 A. Yes.
- 4 Q. Can you name any study that concludes that
- 5 oxidative stress actually causes ovarian cancer?
- 6 A. In vitro studies?
- 7 Q. Yes.
- 8 A. We have published several in vitro studies
- 9 showing that alteration oxidative stress -- and we
- 10 | have identified actually a mechanism by which
- 11 | alteration oxidative stress shut down apoptosis.
- 12 | Q. Let me ask you this: Do you equate association
- 13 on the one hand with causation on the other? Are
- 14 | those two concepts one and the same to you?
- 15 A. Association is different than causation.
- 16 Q. One shows correlation and the other shows actual
- 17 | cause. Is that a simple way of looking at it?
- 18 A. Yes.
- 19 Q. The studies that you were referring to a moment
- 20 ago that you and others have done, those are studies
- 21 that show some sort of an association between
- 22 | oxidative stress and ovarian cancer, but they don't
- 23 | say that when you have oxidative stress cancer will be
- 24 caused. Did I get that right?
- 25 A. Not in all of them. Some studies say there is a

1 | strong association between oxidative stress and

2 ovarian cancer. But I want to say association studies

3 | in the lab, we don't do association studies. We do

4 | mechanism. There are several mechanistic papers

5 | showing these markers of oxidative stress upon

6 | exposure to talcum powder actually changed and mimics

7 | the one that you see in ovarian cancer. And we had

8 established a strong link not only with the oxidative

stress but also for the uncontrolled cell division and

10 | shutdown of programmed cell death.

9

11 Q. I'm talking about oxidative stress. I would

12 | like to keep that focus, if I may?

13 My question to you now is: Is the notion that

14 oxidative stress causes ovarian cancer generally

15 | accepted in the scientific community?

16 A. The exact notion like that, it says it plays a

17 | role in causation of ovarian cancer, yes.

18 Q. And the reason that you made the distinction you

19 | just did is it is one thing to say there are

20 circumstances where we note oxidative stress and it is

21 quite another thing to say that when we see oxidative

22 | stress, cancer will be caused. Those are two very

23 | different things. Right?

24 A. Oxidative stress alteration in the format that

25 | we described has been observed in ovarian cancer

```
143
    patients. So it is there published by us and others.
1
2
            MR. WILLIAMS: Your Honor, is this a good time
    to take our afternoon break?
3
            THE COURT: Sure. That will be fine.
4
5
            THE DEPUTY CLERK: All rise.
6
            (Recess.)
7
            (Continued on the next page.)
    ////
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
```

```
144
            THE DEPUTY CLERK: All rise.
1
 2
            THE COURT: Thank you.
 3
    GHASSAN SAED, resumed.
 4
 5
    CROSS-EXAMINATION (continued)
 6
7
    BY MR. WILLIAMS:
8
         Dr. Saed, there was some discussion today about
    CA-125 levels. Do you recall that?
9
10
    A. Yes.
         You say in your report that CA-125 is a
11
    Q.
12
    clinically relevant biomarker, and that's in your
13
    report at C 17, page 22. Do you recall writing that?
14
    Α.
         Yes.
15
         You are not an expert in CA-125 or its clinical
16
    utility. Correct?
17
          Yes, I'm not an OB GYN/oncologist.
    Α.
          You don't know whether CA-125 is used to
18
    diagnosis ovarian cancer. Right?
19
20
          What I know about CA-125, it is used to follow
21
    the treatment, how effective the treatment for the
2.2
    patient. That's all.
23
          That's not my question. My question is whether
24
    you know one way or the other whether CA-125 is used
25
    to diagnose ovarian cancer?
```

- 1 A. It is not used to diagnose typically.
- 2 Q. You know of no studies showing an association
- 3 between elevated CA-125 levels and an increased risk
- 4 of ovarian cancer?
- 5 A. Yes.
- 6 Q. My question, is that accurate. Do you know of
- 7 | such studies?
- 8 A. Say it again, please.
- 9 Q. You know of no studies showing an association
- 10 between elevated CA-125 levels and an increased risk
- 11 of ovarian cancer; do you? You know of no such
- 12 studies?
- 13 \mid A. I know that CA-125 is used in some cases as a
- 14 | biomarker for ovarian cancer, especially for the
- 15 | patient --
- 16 THE COURT: He asked about studies. Do you
- 17 know of any studies showing an association between
- 18 | elevated CA-125 levels and an increased risk of
- 19 ovarian cancer? Do you know of such studies?
- THE WITNESS: No.
- 21 Q. You would need to defer to a gynecological
- 22 oncologist for that. Correct?
- 23 A. Yes.
- 24 Q. Can we agree, Doctor, that CA-125 is not
- 25 | specific to ovarian cancer?

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- To ovarian cancer what? 1 Α.
- 2 I'll put it this way: You don't know whether Q.
- CA-125 levels can be elevated during menstruation; do 3
- 4 you?
- 5 I know CA-125 is elevated in fibroids, in
- 6 endometriosis, some pregnancies, also.
- 7 It is not unique to ovarian cancer. Right? Q.
- 8 Α. Yes.
- 9 Let me ask you some questions about dose. Ο.
- It's unique to inflammation. 10 Α.
- Let me ask you about dose. Is it true you 11 Q.
- cannot cite any data showing that the talc 12
- 13 concentrations that you used in your experiments are
- 14 similar to or the same level of exposure in women who
- 15 use talc?
- 16 Very hard to correlate the two. Α.
- 17 I asked you whether or not you have data showing
- the talc concentrations in your experiments are 18
- similar to the levels of exposure in women using talc? 19
- What I said is, we don't know how much women get 20
- exposed to talcum powder. 21
- 2.2 Q. In fact, you did not make any effort to
- 23 determine how the concentrations you chose for your
- 24 experiment compare to the level of exposure in real
- 25 life for women who use talcum powder; did you?

- 1 A. I made the efforts to make sure that the doses I
- 2 have used to treat my cells are not toxic and the
- 3 cells are happy when they are there. They have all
- 4 the functions.
- 5 Q. That's not my question. My question is, sir,
- 6 you did not make any effort to determine how the
- 7 | concentrations that you did choose compare to the
- 8 | level of exposure in real life for women who use
- 9 talcum powder. You didn't do that; right?
- 10 A. It's not known the dose that women are exposed
- 11 to in real life, it's not known to me.
- 12 Q. And what you did if you saw there were some
- 13 other studies that used certain doses, and you rattled
- 14 | those off earlier -- you remember 20 and 5 and 20 and
- 15 | so on that you used, right? You used that because
- 16 other studies had used them. Right?
- 17 | A. I started higher, and I tapered it down, and I
- 18 | looked at others, and we found that they are within
- 19 | the same range that I am using.
- 20 Q. Actually, that's not quite what you did; is it,
- 21 sir. You actually started with 1,000 micrograms per
- 22 | milliliter, and that killed the cells; true?
- 23 A. It kills some of the cells, yes.
- 24 Q. And you went from 1,000 to zero, five, 20.
- 25 | That's what you did. Right?

- 1 A. No. I went from 1,000 to 500, and 200, and then
- 2 | I chose those doses.
- 3 | Q. In the end, the doses that you used were the
- 4 doses used by others. Right?
- 5 A. Yes.
- 6 Q. As you sit here, though, you don't know whether
- 7 | the doses that you used, whether the talc
- 8 | concentrations that you used compare to actual human
- 9 exposure in women using talcum powder. Correct?
- 10 A. Correct.
- 11 Q. A few questions on controls.
- 12 You created a solution of talc called DMSO and
- 13 | you described that for the Court this morning. Right?
- 14 A. Yes.
- 15 Q. DMSO is a liquid that can dissolve other
- 16 | substances. Correct?
- 17 A. Yes.
- 18 Q. You used sterile DMSO without talc as a control?
- 19 A. Yes.
- 20 Q. And the reason you used the DMSO solvent by
- 21 | itself was to test for a response in cells that were
- 22 | not treated with talc. Right?
- 23 A. No. We compared cells that were treated with
- 24 DMSO alone; DMSO with talc. We're comparing the two.
- 25 | Q. Your reasoning was if DMSO had an effect on the

- 1 | cells, you would see a response in cells that were not
- 2 | treated with talc?
- 3 A. If there is an effect, yes. You control for
- 4 that effect. That's what a control is for.
- 5 Q. You used a centrifuge to separate the talc that
- 6 | was mixed with the DMSO into two phases, a liquid
- 7 | soluble phase on top and talc particles on the bottom.
- 8 Right?
- 9 A. Yes.
- 10 | Q. Ideally, the liquid soluble phase on the top
- 11 | should be DMSO only with no talc, right, in an ideal
- 12 world?
- 13 A. There is a solubility of talc in DMSO.
- 14 | Q. And that liquid phase overlying the talc
- 15 deposited at the bottom is called supernatant. Is
- 16 | that what that is called?
- 17 A. Yes.
- 18 Q. You tested the supernatant to see if there was
- 19 | an effect even without the presence of talc particles.
- 20 Right?
- 21 A. What I'm trying to say, there is a solubility of
- 22 | particles of talc in DMSO at the level of .1-microgram
- 23 to million; and that is already published. So there
- 24 | is solubility in there, yes.
- 25 Q. When you tested the supernatant to see if there

1 was an effect by the supernatant even without the

2 presence of the talc particles, you found an effect.

- 3 Right?
- 4 A. That's what I'm saying.
- Your Honor, this DMSO dissolved talc; some talc is dissolved in DMSO. That's my answer. To the effect we are seeing, you cannot separate the
- 8 supernatant or the talcum powder.
- 9 Q. What you are saying to Her Honor is you believe
- 10 | the reason you saw an effect was because you could not
- 11 | fully isolate the talc particles from the supernatant.
- 12 | Is that what you are saying?
- 13 A. No. I'm saying some talc may dissolve in the
- 14 DMSO solution and be in the supernatant. That's what
- 15 I'm saying. So the effect could not be isolated if
- 16 | it's talc or DMSO in the supernatant. That's why we
- 17 | combined them.
- 18 Q. Did you do anything to confirm that hypothesis?
- 19 A. We combined them and tested the DMSO alone to
- 20 compare. I'm not interested to see which part of the
- 21 particle is doing the affect. I'm interested to see
- 22 | the whole preparation in DMSO -- the whole preparation
- 23 | means Johnson & Johnson Baby Powder in DMSO versus
- 24 DSMO alone. That's my interest. Further studies may
- 25 | be done to fractionate to see which part does what.

- 1 That's a different study.
- 2 Q. A negative control group is often one in which
- 3 | you would expect to see no response. Right?
- 4 A. Control group, if that's why you have a control
- 5 group, if there is a response, you can correct for it.
- 6 That's the idea.
- 7 Q. My question is about a negative control group, a
- 8 benign substance.
- 9 A. Okay.
- 10 | Q. You are testing to see whether a substance
- 11 | causes a harm. And you also, as a negative control
- 12 | test something known not to cause harm. Are you
- 13 | familiar with that concept?
- 14 A. Yes.
- 15 Q. One example of a negative control would be if
- 16 | you exposed the cell line to an inert substance like
- 17 | cornstarch. Right?
- 18 | A. I don't know if cornstarch is an inert
- 19 substance. I never tested it.
- 20 | Q. And you did not test cornstarch here?
- 21 A. I did not test it.
- 22 | Q. Let me ask you about doing work in triplicate,
- 23 replicability of your work.
- 24 Earlier you discussed the proposal you sent to
- 25 | the plaintiffs' lawyers. You recall that. Right?

- 1 A. Yes.
- 2 Q. The proposal that you sent to the plaintiffs'
- 3 | lawyers said: "All experiments will be performed in
- 4 triplicate." True?
- 5 A. True.
- 6 Q. The manuscript that you submitted to the
- 7 Reproductive Sciences also says, "Experiments were
- 8 | performed in triplicate, does it not?
- 9 A. It does.
- 10 Q. Now, your expert report does not say that your
- 11 | experiments were performed in triplicate?
- 12 A. I don't know. I can't remember.
- 13 Q. I'll make that representation to you.
- Did you in fact perform the experiments
- 15 described in your report three times for the same type
- 16 | sample, for the identical sample?
- 17 A. I need to answer this, your Honor.
- 18 My understanding to experiments is that I'm
- 19 referring to assays, and all the assays are done in
- 20 triplicate. Let's agree on that first. All the
- 21 assays for the study was done in triplicate.
- 22 | Now, let's go -- which I understood from your
- 23 question, are you referring to the assays to the
- 24 experiments or how many cell lines? I just want to
- 25 | clarify that.

- All of the assays are done in triplicate, and this is very clear in the lab notebook.
- 3 | Q. What do you mean by "in triplicate"?
- 4 A. Three times.
- 5 Q. So what you are testifying to is that each one
- 6 of the cells was put into a petri dish and tested
- 7 | three different times?
- 8 A. No. What I'm saying is -- that's why we are
- 9 | mixing up stuff. Assays, like realtime, PCR, like
- 10 | ELISA, like proliferation, all the assays I described
- 11 | in my studies, they all are done in triplicate. What
- 12 | I understood from your question, and correct me, the
- 13 | point that was raised earlier, that traditionally to
- 14 do triplicates you have to take one cell line, and the
- 15 | same cell line split it into three different dishes
- 16 and do the experiments.
- 17 | Q. Did you do that?
- 18 A. I have done that in the past but not for this
- 19 study. For this study I have done what I believe, and
- 20 | I published with it several times, that even more
- 21 powerful six times, not three times. We did it six
- 22 times, six repeated different times. We did it with
- 23 | cell one. We got results. We did it with cell two.
- 24 | We got similar results. We did it with a different
- 25 | cell No. 3. We got the same results. Similar results

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- 1 | were four, five and six. So six different cell lines,
- 2 repeated six different times. We got it similar. In
- 3 | my opinion, this is more powerful than showing the
- 4 effect on one single cell line.
- 5 Q. So we're clear. Each cell line individually was
- 6 | not done three times?
- 7 A. Correct.
- 8 Q. You are relying upon the idea that it is
- 9 powerful to have six different cell lines tested?
- 10 A. Yes.
- 11 | Q. You have done studies, experiments in triplicate
- 12 using what we'll call Version 1, or what you called
- 13 | this morning Version 1. True?
- 14 | A. True.
- 15 Q. You did not do that here?
- 16 A. I did more here.
- 17 Q. You did not do Version 1 you talked about this
- 18 | morning?
- 19 A. No.
- 20 Q. Earlier we discussed the manuscript that you
- 21 | submitted to the Journal of Gynecologic Oncology. The
- 22 | manuscript you submitted to that journal reported that
- 23 you treated the cell lines that you were experimenting
- 24 on with talc for 48 hours. True?
- 25 A. The GYN Oncology?

155 1 Q. Yes. 2 Yes. Α. This is Exhibit A 38. It is page 15. It is the 3 Q. first full paragraph, lines 115 through 116. And 4 there it says that the cells were treated 24 hours 5 later with 100 micrograms per milliliter of talc for 6 7 48 hours. Right? 8 Α. Yes. We also discussed comments submitted by the two 9 experts who reviewed your transcript. I would like to 10 look at those again. 11 12 Let's pull out Exhibit B 23. That's in the 13 first notebook you have; and if you would turn to page 4. You see on page 3 the comments from Reviewer No. 2 14 15 are described, and they carry over to page 4. Do you see that? 16 17 Α. Yes. As it carries over to page 4. It says: 18 Q. "The fact that SNPs were changed following 19 such short exposure to talcum is surprising and makes 20 21 one wonder what the biological effect of such changes 2.2 might be." 23 Did I read that right? 24 Α. Yes. 25 The Journal of Gynecologic Oncology sent its Q.

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rejection letter to you on September 19th of 2018. 1

- 2 Right?
- 3 Α. Yes.
- Now, after that, on January 3rd of 2019, you 4
- submitted a revised version of your manuscript to the 5
- Journal of Reproductive Sciences which ultimately 6
- 7 accepted it for publication. Right?
- 8 Α. Yes.
- Your revised manuscript changed the time from 48 9
- to 72 hours. True? 10
- 11 Α. Yes.
- 12 And that, for the record, is Exhibit B 14, page
- 13 7, the first full paragraph.
- Now, in between your submissions to the two 14
- 15 journals you did not rerun the experiments to increase
- the length of talc exposure from 48 to 72 hours. 16
- 17 Right?
- 18 Α. Yes.
- You did not do that. Right? 19 Ο.
- 20 I did not. Α.
- 21 Your expert report in this matter says that you Q.
- 2.2 exposed the cells to talc for 48 hours. Right?
- 23 Α. Yes.
- 24 And we've got that on the board, and that is, Q.
- for the record, Exhibit C 17, page 16, the first full 25

paragraph. 1 2 Do you recognize that from your report? 3 Α. Yes. My manuscript that I submitted to GYN Oncology was based on my expert report and both have 4 this error in them. 5 6 In the lab notebook, your Honor, I can show 7 you at the page where it clearly describes the 8 experiments, the cell type, how many hours, the details for all the experiments. 9 We'll get to that. 10 Q. I'm just trying to tell you the report was used 11 Α. 12 for my manuscript. That's why it carried over. The report was used for the manuscript? 13 Q. I used part of the manuscript for the report. 14 15 THE COURT: Which is it? Which was it? THE WITNESS: I think the report first and the 16 17 manuscript second. The reference to 48 hours in your report was a 18 Q. typo? 19 20 Α. Yes. 21 Was the reference to 48 hours in the original Q. manuscript submitted to Gynecologic Oncology also a 22 typo? 23 24 Α. Yes. 25 Was that reference to 48 hours everywhere where Q.

- 1 | it was reported?
- 2 A. Not everywhere. In the last section where we
- 3 | did the studies with Johnson & Johnson Baby Powder the
- 4 | last part of the lab notebook, all that study was done
- 5 for 72 hours with zero, five, 20, 100 micrograms per
- 6 mill. All examples are coded. They have an ID
- 7 | number. They are all in the computer and have the
- 8 | time we did the study for.
- 9 Q. Anytime in any writing that you did that it says
- 10 | 48 hours, that was a typo?
- 11 | A. In the initial experiment in the exposure we did
- 12 24, 48 and 72 hours, yes, we did. I cannot say I
- 13 agree to your sentence because in the first initial
- 14 | abstract that we submitted we did 24 hours, 48 hours
- 15 and 72 hours. I cannot remember exactly where is that
- 16 but we did more time points.
- 17 Q. It's a simple question. Right now we are
- 18 looking at your report. It's Exhibit C 17, and it
- 19 says that the cell lines were treated 24 hours with
- 20 different amounts for 48 hours. Correct?
- 21 A. Correct.
- 22 Q. My question is simply that, if we read a report
- 23 of yours or a submission of yours that uses 48 hours
- 24 | as opposed to 72, is that an error?
- 25 A. In this report it is an error. In GYN Oncology

- 1 | manuscript it's an error.
- 2 | Q. Is there anywhere where it says 48 hours that it
- 3 | is not an error?
- 4 A. I think in the initial abstract that we
- 5 | submitted. I'm not sure. I forgot.
- 6 Q. You submitted an abstract to the Society For
- 7 | Gynecologic Oncology. Right?
- 8 A. Yes.
- 9 Q. The abstract you submitted also refers to
- 10 testing for 48 hours. Right?
- 11 A. When was the date of this abstract? The very
- 12 | initial work, your Honor, we did it for 48 hours.
- 13 THE COURT: I didn't get your testimony.
- 14 THE WITNESS: The very initial work that we
- 15 | did, part 1 and part 2 of the lab notebook, that was
- 16 done with different time points. But the one in the
- 17 | manuscript, it's only done in 72 hours, and that's
- 18 | clearly indicated in the lab notebook.
- 19 Q. Let me refer you to your testimony. Tab 1, page
- 20 | 316, lines 3 through 12. You were asked the following
- 21 | question and gave the following answers:
- 22 | "QUESTION: I'm showing you what I'm marking
- 23 as Exhibit 19. Do you recognize Exhibit 19?
- 24 "ANSWER: It looks like the abstract we
- 25 | submitted to SGO.

"OUESTION: This abstract in the middle refers 1 2 to testing done at 48 hours. Is that correct? 3 "ANSWER: 48 hours is a typo everywhere you see it. I acknowledge that." 4 Did I read that right? 5 6 Yes, I was referring to the report and the Α. 7 manuscript. 8 Q. You were referring to --9 The report and the manuscript, and I have to check the abstract, the very first one that we 10 submitted. I can't remember if it is 48 or 72. 11 12 THE COURT: It says 48. He wants to know if 13 it was a typo. But in your testimony you said it was accurate, because early on you only did it in 48. 14 15 MR. LAPINSKI: Your Honor, if I can object for a second because counsel now is referring to an SGO 16 17 publication at the end of 2018, and asking about 48 18 hours in the initial studies that he did that were published prior to that, and I want the record to be 19 20 clear as to the abstracts that are being referred to 21 and where they might have been 48 hours and where they 2.2 might have been 72 hours. 23 THE WITNESS: Your Honor, the very first 24 report that we did was 48 hours. 25 THE COURT: Where is that?

```
THE WITNESS: At the Gynecology Oncology
1
 2
    abstract. I'm talking about the 48 hours being an
 3
    error. I'm talking exclusively only in the report and
    the manuscript specifically -- the manuscript that we
 4
    did submit for GYN Oncology. When I reviewed the
 5
    manuscript for the accuracy of the time, I checked
 6
 7
    exactly the time and the description and everything
8
    was there.
            THE COURT: You did that after you got the
 9
    criticism?
10
            THE WITNESS: After the paper was rejected
11
12
    from GYN Oncology, we submitted the work to
    Reproductive Sciences; and when we submitted the work
13
14
    to Reproductive Sciences, it attracted my attention
    that we did a mistake there.
15
            THE COURT: You went back and looked at it
16
17
    after it was highlighted for you in the criticism?
            THE WITNESS: Right.
18
          As recently as the SGO meeting that took place
19
    Ο.
    in Honolulu a couple of months ago, that the same
20
21
    reference to 48 hours was made?
2.2
    Α.
          The one in Honolulu is the SNP study --
          It is Exhibit Saed 505. It would be in the
23
24
    second binder to your right.
25
            MR. WILLIAMS: Your Honor, I'm asking him to
```

- 1 look at what I want him to look at.
- THE COURT: Please follow the question. Not
- 3 | your lab book. It's Exhibit 505.
- 4 A. I want to look at the original lab notebook.
- 5 | Q. I'm asking you about the abstract.
- 6 A. I see it in front of me.
- 7 Q. This is the abstract presented at this 50th
- 8 | annual meeting of the SGO that happened in March?
- 9 A. No, that's not me.
- 10 | Q. Why do you say it's the wrong manuscript?
- 11 A. I'm not the author here. That's not my work.
- 12 Q. You were not a participant in any of this work
- 13 here?
- 14 | A. Where? Oh, now, no, this is different. There
- 15 | was a different one.
- 16 Q. It's from the same summary. The top of the
- 17 page -- of page 1 was just for the date. But my
- 18 | question is whether or not you listed here in the 12,
- 19 | 16 poster session where your name appears there, that
- 20 the cell lines were treated with talc for 48 hours?
- 21 A. It says that there, yes.
- 22 MR. LAPINSKI: Can we have the page identified
- 23 that this highlight is coming from so we could follow
- 24 along?
- MR. WILLIAMS: Page 94. That's where this is

1 from, your Honor.

2 Where this says 48 hours a couple of months ago Q.

- 3 that was a typo as well?
- This is the SNP studies. 4 Α.
- Is that a typo as well? 5 Q.
- 6 To answer you, I have to go and look at the Α.
- 7 manuscript, what it says in the manuscript.
- 8 Q. In the manuscript or your lab book?
- 9 The Reproductive Sciences manuscript. I don't
- have a copy here. 10
- Q. As you sit here today, you don't know one way or 11
- 12 the other whether you tested for 48 or 72 hours for
- the SNPs? 13
- I don't know. If you let me look. I can't 14
- 15 remember. I need to look at my manuscript. That's
- 16 all I'm saying.
- 17 Q. Counsel may find it for you and ask you about it
- 18 on redirect.
- You wrote 48 hours in your original manuscript 19
- in the Journal of Gynecologic Oncology in August of 20
- 21 2018. Correct?
- 2.2 Α. The abstract, yes.
- 23 You wrote 48 hours in your expert report.
- 24 Right?
- 25 A. Yes.

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- 1 Q. You wrote 48 hours in your abstract to the SGO?
- 2 A. For the SNP studies, yes.
- 3 Q. You wrote 48 hours in a poster presentation as
- 4 | well?
- 5 MR. LAPINSKI: Can we identify the poster
- 6 presentation.
- 7 MR. WILLIAMS: It's the one we just had from
- 8 | the SGO meeting in Honolulu, Exhibit 505.
- 9 MR. LAPINSKI: Can we see the poster
- 10 presentation.
- 11 | Q. Now, you testified your lab books reference
- 12 | 72 hours as the amount of time the talc was tested.
- 13 Right?
- 14 A. Yes.
- 15 Q. Can you cite any other substances that have ever
- 16 been reported to cause DNA mutations after 72 hours of
- 17 | treatment in cell cultures?
- 18 A. Yes.
- 19 | O. What is that?
- 20 A. I can't remember off the top of my head but
- 21 | there are many. We get mutations every day.
- 22 | Q. As you sit here now, you can't remember any?
- 23 | A. What I'm saying, I don't remember a particular
- 24 one but there are many --
- 25 THE COURT: Think of one. You don't need to

1 | give me many.

THE WITNESS: Like, for example, smoking is

3 | linked to a signature of genetic mutations. Radiation

4 is linked to a signature of mutations. I don't know

5 | how soon that will come up, but I know some studies

6 that were major and they found mutations in 72 hours.

7 Q. Do you remember being asked at your deposition

8 | whether you can cite any other substance that has ever

9 been reported to cause DNA mutations after only

10 | 72 hours of treatment, and you could not recall that.

- 11 Do you remember being asked that?
- 12 A. Yes.
- 13 | Q. Since your deposition and up until today, have
- 14 | you had an opportunity to think about and determine
- 15 whether there are in fact other substances that are
- 16 | shown that type of mutation after 72 hours?
- 17 A. No.
- 18 Q. The smoking example that you gave a moment ago,
- 19 can you testify today 72 hours would be sufficient to
- 20 | show the mutations?
- 21 A. No, I can't. I don't know the time.
- 22 | Q. You mentioned a few moments ago the lab books
- 23 mentioned 72 hours. Do you recall that?
- 24 A. Yes.
- 25 Q. Let me ask you about your lab notebooks.

```
166
          Okay.
1
    Α.
 2
          You prepared a lab notebook that corresponds to
    Q.
 3
    the experiments described in your expert report.
    Correct?
 4
 5
    Α.
          Some of it, yes.
          The entries in the lab notebook start in October
 6
    Q.
 7
    of 2017, and they end in October 2018. Correct?
8
    Α.
          Approximately. I'm not sure.
          Let's see what you said in your deposition.
 9
    Page 88, tab 1 of the red book. Lines 9 through 19 on
10
    page 88 you were asked the following questions and
11
12
    gave the following answers:
            "QUESTION: When was this lab notebook Exhibit
13
    No. 2 at the deposition prepared?
14
            "ANSWER: I don't know exact dates.
15
            "QUESTION: Correct?
16
17
            "ANSWER: I don't know. I can't remember.
18
            "QUESTION: Well, the date -- the dates run
    from 10/15/17, to?
19
20
            "ANSWER: All the way to --
21
            "QUESTION: All the way to --
            "ANSWER: October.
2.2
23
            "QUESTION: October or so of 2018.
24
    this notebook prepared over that entire period of
    time?
25
```

"ANSWER: Yes." 1 2 Were those the questions and answers you gave? 3 Α. Yes. Not all of the entries in your lab notebook, 4 5 sir, were prepared at the time the work was being done. True? 6 7 Not true because we're referring, your Honor, to 8 two lab notebooks. I was asked about one of them. The other one here was not in my first deposition, and 9 this is September 26, 2017. So when I went to my 10 first deposition, we had only the lab book that refers 11 12 to the manuscript, and this lab notebook was not 13 there. The lab notebook that you are holding in your 14 15 hand now, what is the first date and last date reflected? 16 17 A. The first date was September 26, 2017. THE COURT: What is the last date that deals 18 with this matter? We're not interested in unrelated 19 20 issues. THE WITNESS: In this matter it deals with 21 October 2018. 2.2 23 THE COURT: Wasn't that the question he just 24 asked you, and you answered in your deposition. It is no different. Is that correct? 25

168 THE WITNESS: Okay. 1 2 The first date is October 2017. The last date Q. 3 is October 2018. Right? 4 Α. Okay. 5 Is that true? Q. 6 Α. Yes. 7 And you have the lab book in your hands as we Q. 8 speak. Right? 9 Α. Yes. Not all of the entries in your lab book that you 10 Q. are holding in your hand right now were prepared at 11 12 the time the work was being performed. True or not true? 13 On the same day? 14 Α. Yes, on the date reflected in the book. 15 Q. 16 Some entries are entered the same day. Others Α. might be a week later or two weeks later. Are you 17 talking about the data entry? 18 Let me refer you to your testimony. 19 Page 87 of your testimony, lines 15 through 20 21, you were asked the following questions and gave 21 2.2 the following answers: 23 "QUESTION: Were all the entries in Exhibit 24 No. 2 prepared at the time that the work was done? 25 "ANSWER: No.

- 1 "QUESTION: When you say no, does that mean
- 2 that there was work done and then the -- later on
- 3 | entries were made in the lab notebook?
- 4 "ANSWER: Correct."
- 5 Were those the questions you were asked and
- 6 | the answers you gave?
- 7 A. Yes. And that's what I just said.
- 8 | Q. There was work that was done and at some later
- 9 point in time entries were made in the notebook
- 10 describing the work. Right?
- 11 A. You are talking about data points?
- 12 | Q. I'm talking about anything that appears in your
- 13 | lab notebook, the work was done and at a later point
- 14 | in time entries are made in the notebook describing
- 15 the work.
- 16 A. We just stick the data that we print out from
- 17 | the computer, yes.
- 18 Q. Yes, the work sometimes was reflected later?
- 19 A. Yes.
- 20 | Q. Some of the entries in your lab notebook were
- 21 made months after the fact. Is that true?
- 22 A. Not true.
- 23 | Q. You were first deposed in this matter on
- 24 | January 23rd of 2019. Do you remember that?
- 25 A. Around that.

- 1 Q. You testified portions of your lab notebook had
- 2 been put together four weeks prior to that deposition.
- 3 | Do you recall saying that?
- 4 A. This lab notebook, yes.
- 5 Q. That's the same lab book that starts in October
- 6 of 2017 and ends in October 2018. Correct?
- 7 A. No. We have two lab notebooks.
- 8 | Q. What lab notebook are you holding in your hand
- 9 now?
- 10 A. This lab notebook starts October 17th.
- 11 MR. LAPINSKI: Can we ask the witness which of
- 12 | the two notebooks he is referring to?
- 13 THE WITNESS: This lab notebook starts
- 14 | October 2017 and goes all the way to October 2018.
- 15 THE COURT: It starts on what month and what
- 16 | year?
- 17 THE WITNESS: This lab notebook starts
- 18 October 2017 and ends October 2018.
- 19 THE COURT: And what is the other lab
- 20 notebook?
- 21 THE WITNESS: The other lab notebook starts
- 22 | September 26, 2017, and ends with October 2017.
- 23 Q. 2017 or 2018?
- 24 A. 2017.
- 25 Q. That is a notebook that --

```
171
            THE COURT: That is a notebook that goes for
1
 2
    one month?
 3
            THE WITNESS: Yes.
            THE COURT: And the other picks up from
 4
    October 2017 to October 2018?
 5
            THE WITNESS: Correct.
 6
 7
            THE COURT: I had names on the binders.
8
            MR. WILLIAMS: I would handle it this way,
 9
    your Honor.
         You've now looked at both of your original lab
10
    notebooks. Correct?
11
12
    A. Correct.
13
         There is no date relating to the work you have
    done after a date in October of 2018 in either of
14
15
    those books. Correct?
16
    Α.
         Yes.
17
         One of those books has its last entry of
    October 2017, a year earlier. Correct?
18
19
    Α.
         Yes.
         You testified in this case that portions of your
20
    lab notebook were put together one month prior to your
21
2.2
    deposition being taken in January of 2019. Do you
    recall that?
23
24
    Α.
         Yes.
25
    Q. Can we agree that four weeks prior to
```

- 1 | January 23rd of 2019 would put us in the last week in
- 2 December of 2018? Can we agree on that?
- 3 A. No. We agree on the date but we don't agree
- 4 | what happened.
- 5 Q. True or not true: There were some entries in
- 6 | the lab notebook that has a last date of October 2018,
- 7 | which entries were prepared and put into that book in
- 8 December of 2018?
- 9 A. The statistical analysis, yes.
- 10 Q. So my original question to you --
- 11 A. That I didn't do.
- 12 Q. Are you disavowing the statistical entries?
- 13 A. No. I'm saying these are done by statisticians.
- 14 | It's a printout from the computer. They emailed it to
- 15 us. We were late in putting it in the lab notebook.
- 16 Q. And the statistical analysis portion is the part
- 17 | that you are certain was actually prepared only
- 18 one month before your deposition was taken. Right?
- 19 A. Added to the lab notebook.
- 20 MR. LAPINSKI: Objection. That misstates his
- 21 testimony. He didn't testify the statistical analysis
- 22 | was performed in December of 2018.
- MR. WILLIAMS: If that's what I said, I
- 24 misspoke. I'll restate.
- 25 BY MR. WILLIAMS:

```
173
          The statistical analysis portion, the part that
1
 2
    was actually placed in the notebook only one month
    before your deposition in this case was done in
 3
    December of 2018. Correct?
 4
          I'm not sure.
 5
    Α.
            MR. LAPINSKI: Objection to the use of the
 6
7
    word "done" related to the statistical analysis. It
8
    misstates the testimony and implies the analysis --
 9
            THE COURT: Let's break it apart.
            When was the statistical analysis done and
10
    placed in the notebook?
11
12
            THE WITNESS: The statistics were done June,
13
    July of 2018, and they were entered in the lab
    notebook later in October.
14
15
            THE COURT: I think you said something was
    entered in December.
16
            THE WITNESS: He said that. I didn't say
17
    that.
18
19
         Let's look at your testimony.
    Q.
          In my testimony I never said anything about
20
    statistical analysis.
21
2.2
            THE COURT: I think it was in today's
23
    testimony.
24
            THE WITNESS: Not statistical analysis.
```

Let's look at your testimony. Tab 1, page 88,

25

Q.

```
174
    line 20 through page 89, line 3:
1
 2
            "QUESTION: It wasn't prepared, put together
 3
    in its entirety four weeks ago?
            "ANSWER: Some of it was, yes.
 4
 5
            "QUESTION: What portions were put together
 6
    4 weeks ago?"
 7
            MR. WILLIAMS: Your Honor, four weeks prior to
8
    the deposition would be four weeks prior to
9
    January 23, 2019?
            "ANSWER: I think the one related to the last
10
11
    portion.
12
            "QUESTION: Can you point me to the pages that
13
    were put together in the last month or so?
            "ANSWER: I can't really exactly remember, but
14
15
    the last, I would say the statistical part for sure."
16
            Were those the questions you were asked and
17
    the answers you gave?
    Α.
         Yes.
18
          We can agree one month prior to January 23rd of
19
    this year would be late December of 2018. Correct?
20
21
         Correct, but I was estimating.
    Α.
2.2
    Q.
          You are responsible for the book?
          Yes, I am. I didn't invent data.
23
    Α.
24
          You don't actually know the dates when the
25
    entries in your lab notebook were put in it; do you?
```

2.2

A. I do know when we sent the data to the biostatistician to run the analysis. I have the emails. I have the exact date I did that, and I have the exact date I received all the analysis from the biostatistician. The only thing we did not do was print out what the biostatistician sent me, the method we used for analysis for statistics, the data for statistics. I did not print it out from the computer from the data he sent me electronically and include it into the lab notebook.

THE COURT: So he is saying the statistical information was placed in it in December; that is what he said. The statistical analysis is what was put in later. He did testify to that. I went back.

- Q. The statistical analysis was placed in the book in December, first month before your deposition. Is that accurate?
- A. When we checked later, it was October 18th, not December. When I checked, your Honor, here in the lab notebook, the statistical data was October 18th. I was inaccurate when I said four weeks before. I was estimating.

THE COURT: You also said it today, though. I want to make sure we are clear. Are you now suggesting your testimony both today and at your

```
176
    deposition about the statistical data being put into
1
 2
    the lab book only a few weeks before your deposition
 3
    was an error?
            THE WITNESS: A few weeks --
 4
 5
            THE COURT: A few weeks meaning the end of
    December?
 6
 7
            THE WITNESS: It was an error, your Honor.
8
            THE COURT: And now you are saying it was done
    in October?
9
            THE WITNESS: Yes, because I looked at the
10
    notebook.
11
12
            THE COURT: You don't have any independent
    recollection?
13
14
            THE WITNESS: From my own memory, no.
15
         We have been talking about the statistical
16
    analysis. Let me ask you about other entries that
17
    appear in your book. Okay?
18
    Α.
         Okay.
          With regard to other entries in the notebook
19
    that have dates, can you tell whether those pages were
20
21
    created on the date listed on the page or whether they
    were created later but backdated to the date the work
2.2
23
    occurred?
24
    A. I will try. I don't know. I can't tell all the
25
    time.
```

```
177
          Take a look at page 90 of your deposition.
1
                                                       This
 2
    is page 90, lines 11 through 20. It's the first tab:
 3
            "QUESTION: With regard to the other entries
    in the notebook that have dates, can you tell whether
 4
    those pages were created on the date listed on the
 5
    page or were they created later but backdated to the
 6
 7
    date the work occurred?"
8
            There is an objection.
 9
            "ANSWER: Yeah, so, again, we do the
    experiment. Sometimes it takes a week or two to write
10
    it in the notebook because we have the data
11
12
    electronically, so I tell you the exact date when they
13
    were put in."
14
            Were those the questions and answers that you
15
    gave?
16
    Α.
         Yes.
17
          Scientists typically do not use white-out to
    hide information and then write over the information.
18
    Correct?
19
20
    Α.
         Correct.
21
          That is not proper laboratory practice.
2.2
    Correct?
23
    Α.
         Yes.
24
          Proper laboratory practice would be to draw a
```

line through whatever was there so that the original

- 1 data would remain intact. Correct?
- 2 A. We have no white-out, just for the record, in
- 3 any of the original data.
- 4 Q. Say that again?
- 5 A. We have no white-out in any of the original
- 6 data.
- 7 Q. When we use data in this context; that could be
- 8 words and not numbers. Right?
- 9 A. The data that we have are all electronically
- 10 generated. The white-outs are in the text in the
- 11 | words that describe methodology.
- 12 Q. What I'm asking you is whether it is appropriate
- 13 when you are describing methodology to use white-out
- 14 | and write over what's described in methodology?
- 15 A. I said no.
- 16 | Q. That's not proper?
- 17 A. Correct.
- 18 Q. So whether we are talking about numbers or we
- 19 | are talking about words describing methodology, it is
- 20 | not proper scientific method to use white-out. Right?
- 21 A. If you do it in the data, there is a big
- 22 problem.
- 23 Q. Now, let's look at some of the changes that were
- 24 made.
- In Exhibit B 13, page 125, which is projected

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on the screen, you see there is an entry where there 1

- 2 is white-out, and the words Johnson & Johnson are
- 3 written over at the white-out. Do you see that?
- Yes, I do. 4 Α.
- 5 That has to do with what product is being
- reviewed. Correct? 6
- 7 Yes. Α.
- 8 In another entry your lab notebook added the
- name of the product tested after the time the rest of 9
- the entries on the page had been entered. Do you 10
- remember that? I'll refer you to page 104 of Exhibit 11
- 12 D-13. Exhibit B-13, page 104.
- 13 Do you have that in front of you?
- 14 Α. Yes.
- 15 Do you see the reference to Johnson's Baby
- Powder with an arrow? 16
- 17 Α. Yes.
- And the arrow points to the word "talc"? 18 Q.
- 19 Α. Yes.
- And then on the line after that there is a 20
- white-out on a number of words, and there is a 21
- 2.2 reference to changing the sterilization method in the
- 23 experiment?
- 24 MR. LAPINSKI: Objection. It misrepresents
- 25 what's on the page. There is no reference to changing

1 a sterilization method.

2 Q. Here is my question. You see there is white-out

- 3 used where the words appear "sterilization under UV
- 4 | light to avoid endotoxins"? Did I read that right?
- 5 A. Yes.
- 6 Q. That's a methodology?
- 7 A. Yes.
- 8 Q. It is whited out and those words appear over it.
- 9 Right?
- 10 A. Yes.
- 11 Q. Look at Exhibit B-15, page 31. For this one on
- 12 page 31, this entry in the lab notebook used white-out
- 13 to remove the name of a particular cell line that was
- 14 | used for the experiment. Is that right?
- 15 A. No.
- 16 MR. LAPINSKI: Objection, your Honor. It
- 17 misrepresents.
- 18 Q. What was whited out here?
- 19 A. What's whited out, I can read through it. It
- 20 | says "cell biologic," which is the description of the
- 21 | cell line that is underneath it. She just misplaced
- 22 | it. That's for normal ovarian epithelial. I can see
- 23 through it. It says "cell biologic, Chicago,
- 24 | Illinois."
- 25 | Q. This entry in the lab notebook you used

```
181
    white-out to remove the name of a particular cell
1
 2
    line?
 3
            MR. LAPINSKI: Objection. It misrepresents.
            THE COURT: The document will speak for
 4
    itself. I got it.
 5
 6
    Q. Your lab used white-out to change multiple dates
7
    from multiple entries in the book. Is that a fair
8
    statement?
 9
    Α.
         No.
    Q. For example, let's look at Exhibit B 15, page
10
    32. Do you see the entry, 9/26/2017.
11
12
    Α.
       Yes.
13
         Do you see that is writing over original
    information?
14
15
    Α.
         Yes.
          The next entry on 9/29/2017 was altered with
16
    Q.
17
    white-out. Do you see that? That's another date
18
    there?
19
    A. Yes.
20
            MR. LAPINSKI: Your Honor, can I ask whether
    or not the doctor has his original notebooks; and, if
21
22
    so, he can look at his original notebooks to see what
    is being referred to.
23
24
            THE COURT: He's got them, I think. Are you
25
    looking at your lab notebook?
```

THE WITNESS: Yes. 1

2 I have 9/26/2017 in here. That's different,

- 3 though. Give me one second, though.
- In the handwriting it would be page 3. Do you 4
- have that? 5
- 6 Α. I get what you are trying to say. There is a
- 7 change in the date with the white-out.
- 8 Q. There was one. Right?
- 9 Α. Yes.
- The next one I would like you to look at is on 10 Q.
- page 33 of the exhibit, if you were using the exhibit 11
- 12 in the book. I think it's on page 40, if you are
- 13 looking at the handwritten numbers on the bottom of
- 14 the page. So if you are using the original, go to
- 15 page 40. Do you see the entry that refers to
- 10/3/2017 with white-out? 16
- 17 A. Yes.
- That date has been altered. Correct? 18 Q.
- I don't know if it is altered. It's just a 19
- simple mistake. 20
- 21 You see white-out was used. Right? Q.
- 2.2 Α. Knowing the nature of my research assistant, she
- is always doing mistakes and white's them out. 23
- 24 There is white-out on the page and handwriting
- 25 over it. Correct?

A. Correct.

- 2 Q. The same thing with the next date: 10/6/2017;
- 3 and the next one: 10/7/2017 is what appears there
- 4 with dates changed. Right?
- 5 A. Yes. I see that.
- 6 Q. If you turn the page, there is another one:
- 7 | October 10, 2017, where the date is changed. Right?
- 8 A. Yes, I see the change.
- 9 MR. LAPINSKI: Your Honor, note my objection
- 10 when the statement is made that something is changed.
- 11 There is white-out there. We don't know whether or
- 12 | not it was changed. There is just a reference to
- 13 | white-out there.
- 14 THE COURT: Let's use common sense. There is
- 15 | no reason to white something out.
- MR. LAPINSKI: There are situations, there are
- 17 changes underneath the white-out. Yes, common sense
- 18 | would say --
- 19 THE COURT: This is in the same place. I
- 20 understand the last one where he said he was moving it
- 21 | down the line to biologic. This looks like he's
- 22 | whiting out a date. I will employ some common sense.
- 23 | Q. Let's talk about computational issues.
- 24 Earlier today, and if we could look at Exhibit
- 25 | B 13, page 122, this was pulled up earlier today by

- 1 | plaintiffs' counsel, and it is on page 122, and you
- 2 | will recall there was a discussion of these entries
- 3 for a particular cell line, and there was an average
- 4 taken. Do you remember that?
- 5 A. Yes.
- 6 Q. If we could pull those out, these three numbers:
- $7 \mid 2.17, 2.46, 2.39,$ and then the average was 2.47, and I
- 8 | was using the normalized numbers. Correct?
- 9 A. Yes.
- 10 Q. Counsel said the proper numbers to use were the
- 11 | numbers over to the left, which have pg/ulRNA.
- 12 | Correct?
- 13 A. I said that.
- 14 | Q. Now, today you said that the computer works
- 15 | these averages, decides what to exclude, and takes an
- 16 average excluding the outlier. Correct?
- 17 A. Correct.
- 18 Q. Now, you have been conducting studies of this
- 19 | sort, I believe, you testified, for a number of years.
- 20 | Right?
- 21 A. Correct.
- 22 | Q. And you had your deposition taken in this case,
- 23 | and you were asked the very same question about
- 24 whether or not these averages were accurate, and you
- 25 gave an answer. Do you remember that?

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```
Yes.
Α.
```

1

2 Now, when your deposition was taken and you were Q.

- 3 asked about this very same set of numbers, you didn't
- say anything about the computer doing it; did you? 4
- No, I didn't. 5 Α.
- 6 Let me ask you to look at page 313 of your Q.
- 7 deposition, line 7, through 315, line 12. You were
- 8 asked a number of questions about this very page, and
- bear with me: 9
- "QUESTION: Why do you only average two of the 10
- three numbers sometimes? 11
- 12 "ANSWER: If we have outlier really high
- different. 13
- "QUESTION: And what's your criteria for 14
- 15 throwing out an outlier?
- "ANSWER: So if you have 4.5, 4.3 and 6.5, 16
- that's an outlier. 17
- 18 "QUESTION: What's your threshold for
- classifying something as an outlier to not include it 19
- in your calculations? 20
- 21 "ANSWER: So if the two numbers match, the
- 22 closer they match and the higher the outlier is, is
- 23 what we determine."
- 24 There has been no reference to a computer yet.
- 25 Right? Can we agree on that?

186 1 Α. Yes. 2 Next question, line 16: Q. 3 "QUESTION: Do you always throw out the outlier of the three values? 4 5 "ANSWER: Not always, not necessarily. 6 "QUESTION: So I'm just trying to figure out 7 what's your criteria for --8 "ANSWER: So if they are like, for example, 9 close, like, for example, here, if we don't know that it is an outlier, like, for example, here, 3.6, 4.3, 10 3.2, it's very hard to determine an outlier, but if 11 12 you have 6 and 6 and 7, it is not hard. "QUESTION: Do you have a certain numerical 13 criteria that you use to classify something as an 14 15 outlier that you are going to exclude from your calculations? 16 17 "ANSWER: I just told you. "QUESTION: What is the numerical value? 18 "ANSWER: I don't have a numerical value. 19 "QUESTION: You just eyeball it." 20 21 There is an objection. 2.2 "ANSWER: No, no, no, please. So I just said, if the two numbers agree, very close, the closer 23 24 the two numbers together, and the more further is the 25 other number, that is considered an outlier to me.

"QUESTION: But, again, you don't have any numerical formula that you follow to make that determination. Correct?

"ANSWER: I told you what I follow."

There is still no reference to a computer.

6 Right?

1

2

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4

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16

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20

21

2.2

- A. My understanding to this is, I was giving general explanations to an outlier. That's what I was trying to do.
- 10 Q. My question is: There was no reference to a computer there. Right?
- A. Not here. I tried, your Honor, to explain why I said that. I thought I was explaining to them, what to me, my understanding what is an outlier in general.
 - Q. And as you sit here today, are you able to tell the Court what the methodology is for choosing to exclude some of the values?

For example, Her Honor pointed out the number that was excluded as an outlier was actually closer to the middle number than the other number with which it was attached. Do you recall the Court pointed that out?

- 23 A. Yes.
- 24 Q. Can you explain to the Court why that was done?
- 25 A. Your Honor, these are all formulas that are done

- 1 electronically. The formula -- you only can tell the
- 2 formula if you click on the column it tells you of the
- 3 | exact formula what it is. Here it is not available.
- 4 | I can't tell the formula. So this formula is
- 5 predetermined and put in the spreadsheet and the
- 6 | spreadsheet calculated automatically. So in order to
- 7 | see the formula, your Honor, I have to click on the
- 8 | Excel file and look at the formula, which I can't do
- 9 here. So the criteria of exclusion is set by the
- 10 | biostatistician as the number that has a significant
- 11 difference than the other two. That's what I just
- 12 | said in my deposition.
- 13 | Q. Are you saying that's what you said in your
- 14 | deposition?
- 15 A. That's what I was trying to say at least. My
- 16 understanding, your Honor, if I can explain, this in
- 17 general, that's my understanding. So that's why I was
- 18 | explaining, as I understood it, not as what is the
- 19 exact formula in the book.
- 20 Q. Let me ask you about your cell proliferation
- 21 | analysis and apoptosis.
- 22 Exhibit A 39, page 9, I'm referring to the
- 23 | bold page numbers at the bottom. There is a chart at
- 24 | the top of page 9. It's Figure 5. You report an
- 25 increase in cell proliferation in response to talc

treatment. Correct? 1

- 2 Α. Yes.
- 3 And the normal ovarian cells are reflected by 0.

- the second bar there, right? 4
- 5 Yes. Α.
- Cell proliferation means an increased number of 6 0.
- 7 cells when taken into account the balance that you
- described between cell division and cell death. 8
- 9 Right?
- 10 Α. Yes.
- 11 Normal cells without cancer can experience a Q.
- 12 temporary increase in cell proliferation in response
- to certain substances. True? 13
- What's the word you threw in there? 14 Α.
- I said normal cells without cancer can 15
- experience a temporary increase in cell proliferation 16
- 17 in response to certain substances or agents. Right?
- 18 Α. Yes.
- In fact, temporary cell proliferation is a 19
- normal response of all cells to agents like talc. 20
- 21 Correct?
- 2.2 I don't know that it is normal. What do you
- describe as "normal"? 23
- I'm actually using your words. Do you believe, 24
- 25 according to your knowledge, that an initial induction

190 of proliferation is a normal response of all normal 1 2 cells to agents? 3 I said initial induction of inflammation. Α. Let's take a look at your deposition. Page 265. 4 Q. By the way, proliferation is correct also. 5 Α. 6 Take a look at page 265, lines 10 through 17 you Q. 7 were asked: 8 "QUESTION: But you agree cell proliferation 9 does not equate to cancer? 10 "ANSWER: Okay. I am answering you. According to my knowledge, transit, transit or, let's 11 12 say, temporary or initial induction of proliferation, 13 it is a normal response of all normal cells to agents. If this response continues now, this is a hallmark of 14 15 cancer. It is indication that this cell is going that route." 16 17 Was that how you answered the question at your deposition? 18 19 Α. Yes. You cannot cite any studies showing an increased 20 0. cell proliferation in women using talc? 21 2.2 Α. How do you measure cell proliferation in women? 23 Are you saying it would not be possible to Q. 24 analyze cell proliferation in women?

I'm not aware of that. You need to extract the

25

Α.

Saed W-tross/Mr. Williams

191

1 cells from women to study that. How would you do that

- 2 in vivo?
- 3 Q. Would it be possible to extract cells from women
- 4 to study it?
- 5 A. It would be after the fact of treated versus not
- 6 treated.
- 7 Q. Wouldn't it be possible to do that type of
- 8 | analysis by extracting cells from women?
- 9 A. You can extract ovarian cancer cells from
- 10 tissues from women, yes.
- 11 | Q. You have called cell proliferation an indirect
- 12 | measure of a transformation to cancer cells. Correct?
- 13 A. Yes.
- 14 | O. It is not direct?
- 15 A. It is an indication that the cell is going in
- 16 this direction.
- 17 Q. It is an indication but it is not certain
- 18 | whether the cell would go in that direction or not.
- 19 Right?
- 20 A. Right.
- 21 Q. You resorted to this indirect measure for
- 22 | purposes of your study here because you never tested
- 23 for neoplastic transformations in the cells directly.
- 24 | Correct?
- 25 A. For me, looking at all the profiles we have

- 1 | seen, all the changes we have seen with Johnson &
- 2 | Johnson Baby Powder and their effect in a
- 3 dose-response manner in different areas, not just
- 4 proliferation. We're talking about oxidative stress,
- 5 inflammation, CA-125, induction mutation, all of this
- 6 in combination with increasing proliferation in this
- 7 | matter, prohibiting apoptosis is a very strong
- 8 | indication the cells have gone this way, yes.
- 9 Q. Strong indication but not causal?
- 10 A. 100 percent causative. It's my opinion it will
- 11 | cause it, yes.
- 12 | Q. What percentage would you say it is?
- 13 A. I don't know. Causing this in my experience and
- 14 | the data as I have seen, I think it is very, very
- 15 | likely to cause cancer, yes, ovarian cancer.
- 16 Q. How likely?
- 17 A. Very likely.
- 18 | Q. And any studies that you have published that say
- 19 | that, that mere cell proliferation means that there is
- 20 a mere association is the same thing as a causal
- 21 | connection -- let me rephrase the question.
- 22 We covered this earlier, but my question to
- 23 | you is: Do you consider an association between a
- 24 substance and ovarian cancer to be the same thing as a
- 25 | causal connection between a substance and ovarian

cancer? 1

2 Isolated incidents like that, no. But provided Α.

- the data that we established and we got, yes. 3
- Q. Let's talk about your data. You did this MTT 4
- 5 proliferation assay. Correct?
- 6 Α. Yes.
- 7 Turn to Figure 5 of your Reproductive Sciences
- 8 article. That's Exhibit A 39.
- 9 Α. Okay.
- I'll direct your attention to page 9, Figure 5. 10
- That's the figure at the top of the page. Right? 11
- 12 A. Yes.
- 13 Below that chart and the bar graphs there in the
- fine print, you describe what Figure 5 is. Right? 14
- 15 Α. Yes.
- 16 In your words it shows that cell proliferation Q.
- 17 is increased in response to talc treatment. Right?
- Right. 18 Α.
- So proliferation was determined by something 19
- called MTT proliferation assay. Right? 20
- 21 Right. Α.
- 22 To conduct that assay you added a reagent, a dye Q.
- to the cell lines that you intended to study. 23
- 24 Correct?
- 25 A. Yes.

194 Some of the cells absorbed the reagent and some 1 2 did not. Correct? 3 Α. Correct. Those cells that absorbed the reagent reduced it 4 Q. to a dye? 5 6 Α. Absorbed the dye. 7 They absorbed the dye itself? Q. 8 Α. Yes. The cells that absorbed the dye are the cells 9 Ο. that are proliferating? 10 A. Viable. 11 12 O. The cells that do not absorb the cells do not. 13 Right? 14 Α. Yes. 15 Basically, you measure cell proliferation by applying a dye to the cells and seeing how much dye 16 those cells did or did not absorb? 17 This is a very well established technique, yes, 18 Α. 19 sir. This is what you did? 20 0. I did, yes. 21 Α. 22 Q. Let's take a look at how you conducted the assay. Please look at Exhibit B 13, the lab notebook, 23 24 page 1-87. 25 There is something pasted into the lab

S104355 cross/Mr. Williams 195 notebook, which is a chart. Right? 1 2 Α. Yes. 3 That shows the intended application of the method -- that is, the MTT cell proliferation assay. 4 5 Right? This is how you are going to go about it? I'm sorry. I missed that. 6 Α. 7 This chart right here, it has at the top 96 Q. 8 wells plate design. Right? 9 Α. Yes. This is meant to set forth the design of the --10 Q. That's the plate you insert into the machine. 11 Α. 12 A wells plate is a physical object like a tray. Q. 13 Right? 14 Α. Yes. 15 The 96 refers to the number of wells in that 16 plate. True? 17 A. Yes. Let me show you an example. That's what it 18 looks like? 19 20 Α. Yes. That has eight rows and 12 wells across the top; 21 Q. 22 and 8 times 12 is why it is called a 96 wells plate.

23 Correct?

24 Α. Yes.

Q. Each of those little circles here is a well. 25

 s_a^{104356} cross/Mr. Williams 196 Right? 1 2 Α. Yes. 3 Your lab notebook includes pictures depicting Q. this type of a well plate at many different places. 4 Correct? 5 6 Α. Yes. 7 Do I need to show those to you? Q. 8 Α. No. I know them. 9 That's a common way of doing it? Q. 10 Α. Yes. These are meant to symbolize a wells plate? 11 Q. MR. WILLIAMS: For the record, we are showing 12 13 pages 1-77 and 1-30; those pages have wells plate examples like those on the board. 14 Now, we see the rows on the left-hand side of 15 each of these images. Each of the rows is assigned a 16 17 letter A through H. Is that standard? 18 Α. Yes. On the top of each plate depicted on these pages 19 we see columns numbered 1 through 12. Right? 20 21 Right. Α. 22 Q. Now, there are handwriting markings on these

examples from page 1-77 and page 1-30. Right?

These are for a different assay, though.

I understand. I'm just -- by way of example,

23

24

25

Q.

s104357Cross/Mr. Williams

this is what it would look like when you are recording 1

- 2 the data. True?
- 3 Α. Yes.
- Let's go back to page 1-87 and the 96 wells 4
- plate design. Like the examples elsewhere in your 5
- 6 notebook, this plate designed chart shows 8 rows,
- 7 letters A through H. Correct?
- 8 Α. Yes.
- 9 And 1 through 12 across the top. Right? Ο.
- 10 Α. Yes.
- But below 7 through 12 across the top, there is 11 Q.
- 12 just an open box because it was your intention not to
- 13 use all of the wells for this experiment. Correct?
- No, there was a standard somewhere. 14
- 15 It was a standard somewhere. What was the
- standard? 16
- 17 A standard to compare how much dye you could Α.
- 18 get.
- All I'm focused on is here we have different 19
- 20 cell lines depicted in the rows that go across A, B
- 21 through H. Correct?
- 2.2 Α. Okay.
- Instead of going all the way across, this is 23
- 24 meant to show that there are not going to be wells
- 25 that are used, 7 through 12 for every one of those

S104358cross/Mr. Williams

- types of cells. There are only going to be three. 1
- 2 Right?
- 3 A. I'm missing your point. I don't understand what

- you are saying. 4
- 5 This is the design right here. I don't see
- 6 anything wrong with it. Ask me a question.
- 7 In row A there is a cell line A 2780. Do you Q.
- 8 see that? And that's underneath columns 1 through 3.
- 9 A. Untreated.
- Q. The "UNT" refers to untreated? 10
- 11 Α. Yes.
- 12 Q. And the B row refers to the same cell line
- treated with talc. Right? 13
- 14 Α. Right.
- 15 And this is only for the three cells in columns
- 1, 2 and 3. Right? 16
- 17 Α. Three times, yes.
- What this is depicting is that for the cell line 18
- that is entitled EL-1, the experimenters are going to 19
- use wells 4, 5 and 6. Correct? 20
- 21 4, 5 and 6, yes. Α.
- 22 Q. And row A is for the untreated; row B is for the
- treated. Correct? 23
- 24 A. Correct.
- Q. Now, the cell lines that are depicted here are 25

199 the same cell lines that we discussed -- are the same 1 2 cell lines that you used for all of your studies that 3 you did for this matter. Correct? 4 Α. Yes. Is that right? 5 Q. 6 Α. Yes. 7 "UNT" is for untreated. Right? Q. 8 Α. Yes. And the 100 micrograms per milliliter is for 9 those being treated with talc. Correct? 10 Correct. Α. 11 12 Now, let's look at the normal ovarian cancer 13 cell line untreated. That is Row G. Correct? 14 Α. Yes. 15 And the normal ovarian treated is Row H? Q. 16 Α. Yes. 17 There is not a 9th row here. Can we agree on 0. that? There is no Row I on this well plate design. 18 True? 19 20 Α. Yes. 21 We've talked about your 96 well plate design, Q. and the intended application of your proliferation 22 23 assay. 24 I want to talk to you now how you actually 25 applied it and how you applied your methodology.

S104360 cross/Mr. Williams

Please turn to page 1-88 of your lab notebook, 1

- 2 Exhibit B 13. This page depicts three things: at the
- 3 top it has a chart where there is handwriting above it
- that says "raw data." Correct? 4
- 5 Α. Yes.
- This refers to the raw data that actually was 6 Ο.
- 7 collected by you and your colleagues and analyzed in
- 8 conducting the MTT proliferation assay for your
- publication Exhibit A 39. Right? 9
- Right. 10 Α.
- The numbers in this chart are the raw data. 11 Q.
- 12 Right?
- 13 Α. Right.
- There are six columns here on your raw data 14
- chart. Correct? 15
- 16 Α. Yes.
- 17 0. And that is consistent with the wells plate
- design that we just look at on the previous page, page 18
- 187. Right? 19
- 20 Α. Yes.
- 21 By "raw data," you are referring to the data Q.
- 22 that you collected and analyzed. Right?
- 23 Collected. Analyzed is the next. Α.
- 24 Let's count together the number of rows that
- 25 appear here.

S104361 Cross/Mr. Williams

1 Would you agree there are nine rows here -- 1,

- 2 2, 3, 4, 5, 6, 7, 8, 9 rows. Do you agree?
- 3 Α. Yes.
- Now, a 96 well plate has only eight rows. 4 Wе
- established that. Correct? 5
- 6 Α. Correct.
- 7 And if there were actually nine rows times 12,
- 8 that would be a 108 wells plate design. Right?
- 9 Right. Α.
- Did you use a 108 wells plate design here? 10 Q.
- No, I did not. 11 Α.
- Unlike the plate design on page 1-87, the raw 12 Q.
- 13 data does not assign a letter for each row. Correct?
- 14 Α. Yes.
- 15 On your cell design there is an assignment of a
- 16 letter for the different cells that are going to be
- 17 used. Correct?
- Say that again, please. 18
- For example, "normal ovarian untreated" is row 19 Ο.
- G, columns 1 through 3. Right? 20
- 21 Α. Yes.
- 22 Q. If we go to the actual raw data, can we agree
- 23 that there is no letter that is assigned?
- 24 Α. Yes.
- 25 And as per what the data records, all of these Q.

Saed - Closs/Mr. Williams

- 1 | numbers start with a zero. There is a decimal point,
- 2 and then there is a number that appears after that.
- 3 Right?
- 4 A. Yes.
- 5 Q. The higher number reflects higher levels of cell
- 6 proliferation. True? A lower number reflects a lower
- 7 | number of critical proliferation. Right?
- 8 A. Yes.
- 9 Q. The higher the number the more proliferation.
- 10 True?
- 11 A. It is not as straight as you think. There is
- 12 | also a correction factor. Go to the actual
- 13 | calculation.
- $14 \mid Q$. Go to page 1-88 in the center of the page.
- 15 A. This is how the data is calculated.
- 16 Q. This is how it is actually reported. Right?
- 17 A. This is how it is calculated too.
- 18 Q. Am I correct that the reported data that we're
- 19 looking at here for each of the different cell types
- 20 draws its information from the raw data?
- 21 A. Yes.
- 22 | Q. Without the raw data, one cannot fill out this
- 23 chart, which is the actual reported data from which
- 24 | you prepared the bar chart that's at the bottom of
- 25 | page 1-88. Right?

s104363cross/Mr. Williams

1 Α. Yes.

- 2 I just want to be clear. The same data that Q.
- 3 appears in the middle of the page on page 1-88 is the

- data from which -- the data that you used in preparing 4
- Figure 5 of your manuscript and the article we have 5
- 6 been talking about?
- 7 There is something missing in the middle. Α. Yes.
- 8 Q. Let's pull out the middle.
- 9 THE COURT: The folded piece of paper.
- What's on the folded piece of paper? 10 Q.
- The graph that's established directly from the 11 Α.
- 12 data.
- 13 Very good. Now, the first three columns of data
- 14 -- I wanted to go back to the middle of the page, the
- 15 actual reported data.
- The first three columns of data are identified 16
- 17 by the letters OD, and the numbers 1 through 3.
- Right? 18
- Optical different 1 triplicate, yes. 19 Α.
- 20 "OD" refers to optical different. Right? Ο.
- 21 Α. Yes.
- 22 I'm going to refer to this chart, the one that Q.
- has all the cell charts that you reviewed, and has 23
- 24 optical different from the numbers you reported on the
- 25 raw data as on this reported data. Is that accurate?

- 1 A. Okay.
- 2 Q. We put a slide together that has the plate
- 3 design, the raw data, and the reported data charts.
- 4 Is that okay with you? We already talked about all
- 5 three of these. Right?
- 6 A. I would rather use the middle figure in my lab
- 7 notebook.
- 8 Q. The middle figure in the lab notebook is the one
- 9 | that's reported at the bottom here. Right?
- 10 A. Yes.
- 11 MR. LAPINSKI: Your Honor, note our objection.
- 12 | That's not all the raw data.
- 13 A. That's part of the figure, yes. This is the
- 14 | whole figure from here to here.
- THE COURT: It has a colored graph at the end?
- 16 THE WITNESS: He's taking only this part, half
- 17 | the numbers.
- 18 Q. If we could, let's go back to the reported data,
- 19 which is on page 1-88, if you would blow up the middle
- 20 | section?
- MR. LAPINSKI: Your Honor, just for the
- 22 | record, on the right-hand side of that image, you
- 23 | could see it is covered, and there is additional data
- 24 underneath it.
- THE COURT: There is one last column. That's

```
205
1
    correct.
 2
            MR. WILLIAMS: Your Honor, can I approach?
 3
            THE COURT: Yes.
    BY MR. WILLIAMS:
 4
          In the original book there is a chart that
 5
 6
    appears over to the right that did not appear with the
 7
    copies that has talc treatment. It is in a graph. It
8
    has talc treatment, 100 micrograms per millimeter on
    the X axis, and it has cytotoxicity by percentage
 9
    along the Y axis.
10
            Did I accurately describe what is not depicted
11
12
    in the copy?
13
    Α.
          Yes.
14
            That's just the way the copy was made.
15
          Is it true, sir, the optical densities hereto
16
    are the data that is reported in your report?
17
    Α.
          Yes.
          For ease of reference --
18
    Q.
          For the data that is reported here -- the graph
19
    that you just described that is going to present
20
    percentage of cytotoxicity. Whereas, the graph of the
21
2.2
    one presented in the paper, which is underneath it, is
    percent of cell proliferation above baseline.
23
24
          Are you saying the numbers that appear in the
25
    first three columns of OD 1, 2 and 3 do not get
```

- 1 | factored into the figure at the bottom of the page?
- 2 A. They do. They are the basis of the figure.
- 3 | These are measuring the cytotoxicity. Your Honor, we
- 4 have this methodology determines the number of viable
- 5 cells, and by default, if you have 20 percent viable,
- 6 there is 80 percent toxicity. This figure shows
- 7 percentage of cytotoxicity, the number of killed
- 8 cells.
- 9 Q. I can't hear you.
- 10 A. People have 100 cells, 25 percent of cells are
- 11 viable, 75 percent of cells would be dead. So here
- 12 the assay is calculating percent of toxicity, how many
- 13 dead cells. In our report we wanted to show how many
- 14 | viable cells, which we used the data to extrapolate
- 15 how many viable cells.
- 16 Q. Let me focus your attention, if we could go back
- 17 | to what we prepared with the three different pieces.
- 18 | I just want to show where we are drawing the
- 19 | information from. That's the point I'm trying to
- 20 make.
- 21 Let me focus your attention on the A 1 well,
- 22 | the very first row and column. That is for the A-2780
- 23 untreated cells, correct, and the number drawn out
- 24 | there is 0.1764 in what we have given row A for column
- 25 | 1. Right?

Finally, if you look at the bottom chart, that
is the number as what is set forth in the reported
data for optical different 1 and for A2780 untreated.
Is that correct? That's where the information is

If we look at the raw data which is depicted in the center of the screen, the result for the first well, meaning the first row and the first column, has a result of .1764. Correct?

10 A. Yes.

drawn?

5

6

7

8

- 11 Q. And if you look at the bottom chart, the

 12 reported data, the first well in the first row and

 13 column under OD 1, we see that is from the very same

 14 A2780 untreated cell line, and it is the same value

 15 that is placed in the first column. Is that accurate?
- 16 A. Yes.
- Q. All I'm trying to establish, sir, is the information depicted on the reported data is drawn from the raw data, the row and column that corresponds. Is that accurate?
- A. Yes. But in this case we ran an additional one, an additional plate. If we don't have enough, we always run an additional one.
- Q. Now, let's look at the top table again with the plate design. The amount for well is for the EL-1

S104368cross/Mr. Williams

untreated cells. Correct? See where I'm talking 1

- 2 about at the top of the screen. See that?
- 3 Α. Yes.
- All I'm trying to say is that this is the cell 4
- line that you are using, correct? Row A is untreated 5
- for the EL cell line; B is the treated. Right? 6
- 7 Α. Okay.
- 8 And now let's look at the raw data that appears
- 9 in Row A-4. It's .1616. Do you see that in column
- No. 4? 10
- Α. 11 Yes.
- 12 At the bottom, if we look at the EL cell line,
- 13 that same value point, .1616 is placed there. Is that
- where that information came from? 14
- 15 Α. Okay.
- 16 Are you with me so far? Q.
- 17 Α. I'm trying.
- So you assigned cell lines to specific wells, 18
- and you took the data from the raw data chart and put 19
- it into the reported data chart. That's what 20
- 21 happened. Right?
- 22 Α. I'm completely lost, sorry.
- You assigned the cell lines to a particular 23
- 24 well. This is well A-4. We just talked about that.
- 25 Right?

s104369cross/Mr. Williams

- 1 Α. Okay.
- 2 If we look at the raw data, A-4 there is a value Q.

- 3 there, .1616. Right?
- 4 Α. Right.
- 5 Q. Then at the bottom for the EL-1 untreated, that
- 6 same value appears. Right?
- 7 Α. Right.
- 8 What is supposed to happen is that this chart,
- the cell type chart which is the reported data is 9
- supposed to reflect the data that is set forth here 10
- from the raw data. 11
- 12 Α. Yes.
- Let's use the normal ovarian cancer line as an 13
- 14 example. The normal ovarian cancer line is supposed
- 15 to be row G, columns 1 through 3. Right?
- 16 Α. Yes.
- 17 And Row H is supposed to be the normal -- is the Ο.
- normal ovarian treated cells. Right? 18
- 19 (No response.) Α.
- I'm looking at the top of the plate design. 20 Ο.
- 21 Α. Yes.
- 22 Q. Look where I'm pointing the laser. The plate
- design calls for Row H and wells 1 through 3 to be 23
- 24 used for the normal ovarian treated cells. Is that
- 25 correct?

- 1 A. Ask your question, please.
- 2 | Q. I'm trying to ask you whether we have it right
- 3 | -- whether this information that appears in Row H, the
- 4 8th line down, and column No. 1 is for the normal
- 5 | ovarian untreated cells?
- 6 A. 0.103, 0.115 --
- 7 Q. It's supposed to be treated cells. I misspoke.
- 8 | Row G is supposed to be for the normal ovarian
- 9 untreated cells. Right?
- 10 A. No.
- 11 | Q. This is your methodology. Right? So you tell
- 12 | me what is supposed to be in Row G, columns 1 through
- 13 | G, are they normal ovarian cells or are they some
- 14 other type of cell line?
- 15 A. Let me see. Let me think.
- 16 (Pause.)
- 17 Q. It's a simple question.
- 18 A. It's not a simple question. It took you 3 hours
- 19 to say the question. I need to look at the data and
- 20 | see what's happening.
- 21 Q. I'm not asking about the data. I'm asking about
- 22 | the design for your experiment.
- In the design for your experiment there is
- 24 | supposed to be a well that is assigned for Row G,
- 25 | columns 1 through 3 for normal ovarian untreated

- 1 cells. True or not true?
- 2 A. I see 1. I see the .103 is the untreated
- 3 normal, and the .225 is the treated normal. That's
- 4 what I see here.
- 5 Q. What are you looking at, sir?
- 6 A. I'm looking at the chart in my data here.
- 7 Q. Are you looking at the raw data?
- 8 A. In the middle, the chart in the middle with the
- 9 graph.
- 10 Q. Let's pull out the bottom on this page, if we
- 11 could.
- 12 Now, do you see here in Row G, which was
- 13 | supposed to be for the untreated cells, there is a
- 14 | number .1244.
- 15 MR. LAPINSKI: Your Honor, it's counsel that
- 16 put the amount through I and labeled the cells. It
- 17 doesn't mean Row G is supposed to be associated with
- 18 that.
- 19 BY MR. WILLIAMS:
- 20 | Q. Well, now, let's go to the top here. Is this
- 21 | your plate design or is it not? The top of the screen
- 22 | which depicts what is on page 1-87 of your lab
- 23 | notebook, which has a cutout to describe the
- 24 | methodology for your experiment assigns certain types
- 25 of cell lines to certain rows and columns; does it

S104372cross/Mr. Williams

not? 1

- 2 To describe the sequence. Α.
- 3 And the sequence you are referring to is the Q.
- sequence for the 96 cell design; right? The actual 4
- 5 tray where the samples are placed and tested. Right?

- 6 Α. Yes.
- 7 G-1, 2 and 3 are for untreated. True or not
- 8 true?
- 9 G is for untreated, yes.
- H is for treated. Right? 10 Q.
- Yes. That's supposed to be. 11 Α.
- 12 Plaintiffs' counsel just said that we were the Q.
- 13 ones who assigned these letters to the rows. Did you
- 14 hear that a moment ago?
- 15 Α. Yes.
- 16 Without our adding that, how would you be able Q.
- 17 to look at this raw data without looking at your cell
- design and figure out where the data should be placed? 18
- 19 I think I can answer that. As you said, this is
- not an eight well. This is nine, first of all. 20
- 21 think the last one, the H is referred to the blank
- 22 that we used for that plate --
- 23 H is referring to? Q.
- 24 A blank. And then there is another plate ran
- 25 that we put the data in here for the I, the raw data,

- 1 | transferred it to there, if I remember correctly.
- Q. Could you point the Court to your lab notebook
- 3 | describing what you just said?
- 4 A. Yes.
- 5 Q. Tell us the page.
- 6 A. As you just said, the 96 well plate will go
- 7 | eight rows vertical and nine rows horizontal. Eight
- 8 | times 12 is 96. Here we have nine additional ones.
- 9 Q. You have nine what?
- 10 A. Nine vertical columns.
- 11 | Q. There are actually 6, 1 through 6 and 7 through
- 12 | 12 are not listed. Right?
- 13 A. Okay. Here we have one, A,B,C, 1, 2, 3, 4, 5,
- 14 6, 7, 8, 9 rows.
- 15 Q. I think we are mixing up rows and columns. Rows
- 16 vertically in your cell design are each given a letter
- 17 | A through H. Right?
- 18 A. Can I talk now? Can I talk?
- 19 Q. I think we have to go with questions and
- 20 answers.
- 21 THE COURT: I think he was just trying to
- 22 | clarify we're all on the same page. Do we currently
- 23 have a question pending?
- $24 \mid Q$. Here is the question: There are eight rows here
- 25 | with A through H, and that covers all of the six

- 1 | different cell lines that you analyzed. Right?
- 2 A. Excluding the control that has to be run with
- 3 | it.
- $4 \mid Q$. Are you saying line I, the 9th line is the
- 5 | control?
- 6 A. Line H is the control.
- 7 Q. Where does it say in your book that line H is
- 8 | the control?
- 9 A. Each plate has to have a control; each
- 10 experiment has to have a control with it. These are
- 11 | labeled cell lines treated, untreated, which are
- 12 ovarian cancer cells; untreated/treated normal ovarian
- 13 untreated/treated; and when she did the experiment,
- 14 | she found out these are eight, and she needed to run
- 15 | an additional line, which is a control, and that's the
- 16 H. So she did that, and she ran the I, which we call
- 17 | the I here in another plate, and for raw data we put
- 18 | it all together, so we could export it and analyze it.
- 19 Q. Take a look at your lab notebook and point out
- 20 to the Court that it says the methodology is to run
- 21 seven tests, then do a control, and then an eighth.
- 22 | In other words, other than what you say just now, how
- 23 | would one know that this row, Row H is meant to be a
- 24 | control, and Row I, .225, is meant to be something
- 25

else?

- 1 A. Your Honor, Row I is not part of the plate
- 2 because the plate maximum capacity is 8 by 12.
- 3 Q. Here is the point. Let me ask you this. Let's
- 4 | put up the demonstrative with the plate and the raw
- 5 data. When we draw numbers here from the raw data and
- 6 | we place it into the reported data, do you see with me
- 7 | the numbers from Row A, column 1, .1764 is placed here
- 8 | in the reported data in row A, column 1? Can we agree
- 9 on that?
- 10 A. I agree.
- 11 | Q. For the normal ovarian cancer untreated and
- 12 treated, the number that is drawn for the normal
- 13 ovarian cancer untreated .103 is drawn from Row H. Do
- 14 | you agree with me there? .103 here, Row H, column 1
- 15 is reported as normal ovarian cancer untreated. True
- 16 or not true?
- 17 A. 0.13?
- 18 Q. 0.103 in the raw data is on the eighth row.
- 19 | Correct?
- 20 A. Yes.
- 21 Q. And it is placed in the normal ovarian cancer
- 22 | untreated cited line. Correct?
- 23 A. Yes.
- 24 Q. But here in your design, Row H is for treated
- 25 | normal ovarian cells; is it not?

A. Okay. Yes, let me explain. It is not. She designed and drawn the eight by six. That's 96. She found out if she placed all these cells in the plate down, you will not have a place for control. So what she did, she excluded the last one, which is the normal ovarian treated, and ran a blank with the experiment. If you cannot run a blank with the experiment, that's a problem. Then she ran another plate with the treated ovarian cancer cells -- I'm sorry, normal ovarian cells, and added the data to the

Q. Can we agree that what you just described, what she noticed, what she added is not set forth at all in your notebook?

raw data and computed the calculations.

- A. It's obvious, like the maximum capacity of the 96 well plate, as you indicated, is only eight rows, and we have eight samples, and we need a control. So she decided to run the control with the seven samples and run the other one in the next plate.
- Q. Now, you say that the control is the eighth sample and not the ninth. How do you know that?
- 23 Right? We have eight cells. So we have to remove one

Because I just answered you. It's eight lines.

- 24 cell in order to run the blank. That's what I'm
- 25 saying.

Α.

- Why couldn't she just put the blank in the ninth 1 2 cell? 3 There is no ninth cell. THE COURT: You just said you did run a ninth 4 5 correctly. I'm going to have to stop this.
- 7 THE COURT: Every minute we go on it gets more confusing on this issue.

THE WITNESS: You are right.

You said you ran seven, maybe the eighth one in the control and the ninth ran that other plate. Now you are telling me there is no such thing.

MR. WILLIAMS: Can we get to the punch line?

THE COURT: I'm lost.

6

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21

2.2

23

24

25

MR. WILLIAMS: If we go to a demonstrative, I think it will become clear to the Court. Can we put up the demonstrative that has the plate design and the raw data, both of them, please.

Here is the point. The untreated talc, if one looks at the raw data, has higher values than the treated talc. If you look at the raw data, this is how it is depicted. And the added line has .225, .2248, .2232?

In the reported data, the untreated talc has lower values than the treated talc. But in the raw data, the treated talc has lower values than the

2

3

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5

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21

25

218 untreated talc, unless what Dr. Saed is saying, this ninth row was added -- the eighth row was used suddenly as a blank, and the ninth is meant to depict something different than the cell design. THE COURT: That's what I'm trying to figure out, what this ninth row is. THE WITNESS: There is no ninth line. It's a 96 well plate. THE COURT: What is that? There are numbers put in there. There has to be something. THE WITNESS: This is a demonstration of raw 12 data. That is not a demonstration of drawing a plate. 13 THE COURT: We'll go back to questions and 14 answers. 15 BY MR. WILLIAMS: Q. Let me go back to the cell design. You agreed 17 with me earlier that the wells plate design indicated that Row H, columns 1, 2 and 3 were for treated normal ovarian cells and Row G was for untreated. We then have raw data. And here the seventh row, Row G, has a 20 value, which according to your wells plate design, 2.2 should be for normal ovarian untreated. So let me ask 23 that question: 24 How can one tell by looking at the raw data

which of the cell lines it relates to?

- 1 A. My answer is that the first one is a
- 2 representation of what samples that will be tested,
- 3 | that we will be testing. And when we did that, we
- 4 have two, four, six, eight samples. So we have eight
- 5 rows down. When we figured it out, we found we needed
- 6 to do a control. So she eliminated the last one and
- 7 | ran it separately in another 96 well plate and
- 8 | combined all the data together.
- 9 Q. Why not do a control with a ninth row?
- 10 A. There is no ninth row. You just said the
- 11 | maximum you could get is a 96 well plate.
- 12 | Q. Why do you pick in the raw data the control as
- 13 | the second-to-last as opposed to the last row?
- 14 | A. No, the control is the last row. The last row
- 15 | in the 96 well plate. If you count, it will be H.
- 16 You made up I. I don't know where you got I from.
- 17 Q. You are testifying the last value here, .225 is
- 18 | the control?
- 19 A. No. I'm testifying that H value is the control.
- 20 | O. And I is -- the ninth row is?
- 21 A. The ninth is another -- when we found out there
- 22 was no room for the sample to run, we ran it in
- 23 another 96 well pate, and we put the data here.
- 24 MR. WILLIAMS: Let me stop on this topic. I
- 25 | have one other topic after this if I may.

- 1 Q. If you look at the lab notebook, other than what
- 2 | is depicted on the screen with the 96 wells plate
- 3 design, which assigns a row and a column to each of
- 4 | the different cell types, where in your lab book does
- 5 | it describe how your assistant, your colleague is
- 6 going to use the control sample?
- 7 A. When you have eight samples to run and there is
- 8 | no room for the control, the practice in our lab, to
- 9 eliminate the last sample and rerun it with another
- 10 | plate. That's what we did.
- 11 THE COURT: You said the practice in your lab.
- 12 | How would someone outside of your lab know that is
- 13 | what is going on?
- 14 THE WITNESS: Because there is no space for it
- 15 on the plate.
- 16 Q. But there is space in your lab notebook for
- 17 | someone to describe what your methodology would be so
- 18 | that someone who is looking at this and trying to
- 19 replicate it can follow it. Right?
- 20 A. Correct.
- 21 | Q. And there is no description that says, We're
- 22 | going to go through seven. We're going to apply those
- 23 to each of the rows and columns that we've indicated
- 24 | up above on the previous page in our cell design, but
- 25 when we get to the eighth, we are going to then run a

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221
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control and put that into the eighth line and going to
1
 2
    put the actual data later on --
 3
         Rerun another plate.
    Α.
            THE COURT: We understand that's what you are
 4
 5
    saying. The question is --
            THE WITNESS: It's not in the book, no.
 6
 7
            THE COURT: We got the answer. Let's move on.
8
            MR. LAPINSKI: Your Honor, can we take a
9
    little break, please.
            MR. WILLIAMS: I have two different topics.
10
11
            THE COURT: Let's give the break now.
12
            MR. WILLIAMS: It was my understanding we
    would have double the time of the direct exam, so
13
    double would be four hours for cross-examination.
14
15
            THE COURT: You will. He's asking can we do a
    break now. Remember he's under cross, and please
16
17
    don't speak to your witness.
18
            MR. LAPINSKI: I averaged about 3 hours
    45 minutes, so if Mr. Williams is to finish up in
19
20
    15 minutes with the next two topics he has, that's
21
    fine.
2.2
            THE COURT: All right.
23
            THE DEPUTY CLERK: All rise.
24
            (Recess is taken.)
25
            (Continued on next page.)
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222
            THE DEPUTY CLERK: All rise.
1
 2
            THE COURT: Thank you.
 3
    GHASSAN SAED, resumed.
 4
 5
    CROSS-EXAMINATION
 6
 7
    BY MR. WILLIAMS (continued)
8
    Q.
          Last topic, sir.
 9
            On DIRECT EXAMINATION you were asked some
    questions about financial disclosures, and you
10
11
    discussed the amount of money on cross-examination
12
    that plaintiffs' counsel paid to you for your work.
13
            First question: The amount paid to you by
14
    plaintiffs' attorneys for writing the manuscript that
15
    formed the basis for your report and your publication
    was between 36,000 and 42,000 dollars. Correct?
16
17
    Α.
          I can't remember exactly.
          You initially submitted your manuscript to the
18
    Journal of Gynecologic Oncology. Right?
19
20
    Α.
          Right.
21
          This is Exhibit A 38. Page 23.
    Q.
2.2
            It said the authors have no conflict of
    interest to disclose. Correct?
23
24
    Α.
         Correct.
25
         By the time you submitted your original
    Q.
```

- 1 | manuscript to the Journal of Gynecologic Oncology,
- 2 | plaintiffs' counsel paid you tens of thousands of
- 3 dollars for your work. Right?
- 4 A. Yes.
- 5 | Q. Is there any doubt in your mind about that?
- 6 A. No.
- 7 Q. The statement you had no conflicts of interest
- 8 | to declare was not true, was it?
- 9 A. It is true. I believe I have no conflict of
- 10 | interest to declare because this work, your Honor, is
- 11 | completely funded by my lab from my fund.
- 12 | Q. You just said a moment ago your work was
- 13 | completely funded by your lab. You were in fact paid
- 14 to write the manuscript; were you not?
- 15 A. I was paid for my time, extra time that I spent
- 16 doing the work for Beasley Allen. But the whole work,
- 17 | all the lab supplies, everything I paid for from my
- 18 own lab.
- 19 | Q. I'm sorry.
- 20 A. I paid for all the supplies from the lab and the
- 21 salary of my employees from the discretion fund of my
- 22 | lab. So I believe I have no conflict of interest to
- 23 report. I reported, I disclosed my time that I spent
- 24 | working with Beasley Allen in this case to my
- 25 | university that I work for, and I don't see it as a

```
conflict of interest I should disclose.
1
 2
            THE COURT: Doctor, you were paid for, as you
 3
    put it, extra hours or overtime. I wasn't quite sure
    what that meant because, in the academic field, I
 4
    don't think of it as overtime; but you were paid for
 5
 6
    some of your hours in doing the manuscript. Correct?
 7
            THE WITNESS: Correct.
8
            THE COURT: We have an answer. We could move
 9
    on.
    BY MR. WILLIAMS:
10
          The revised version of your manuscript you sent
11
    Q.
    to the Journal of Reproductive Sciences included a
12
    section entitled, "Conflict of Interest." Right?
13
            MR. WILLIAMS: This is Exhibit B 14.
14
15
          Which journal is this?
    Α.
16
          This is the Journal of Reproductive Sciences.
    Q.
17
    There is a section called, "Conflict of Interest"; and
18
    on page 14 it says:
            "The corresponding author Dr. Ghassan Saed
19
20
    acted as a consultant regarding this topic for a fee.
    Otherwise, the authors declare there are no conflicts
21
    of interest."
2.2
            Is that what it said in the conflict of
23
24
    interest statement?
```

A. Yes.

- 1 Q. You personally prepared the conflict of interest
- 2 section in the revised manuscript. Right?
- 3 A. What do you mean? I don't understand
- 4 "personally prepared."
- 5 Q. Did you, Dr. Saed, prepare the conflict of
- 6 interest section that appeared in the Reproductive
- 7 | Sciences manuscript?
- 8 A. Yes.
- 9 Q. You did not identify who you consulted for.
- 10 Right?
- 11 A. Right.
- 12 Q. You did not disclose your consulting work in the
- 13 | matter was ongoing?
- 14 A. I didn't need to.
- 15 Q. You did not make that disclosure?
- 16 A. I didn't need to disclose that.
- 17 Q. And you did not disclose that?
- 18 A. Sure.
- 19 Q. You did not disclose the fact you consulted in
- 20 | litigation involving talc and ovarian cancer. Right?
- 21 A. Not here. Again, I said in my opinion I don't
- 22 | have a conflict of interest, and I did this because I
- 23 | was criticized by Johnson & Johnson lawyers not to put
- 24 | that. So I said I'm not hiding anything. I will put
- 25 | it.

- Q. Can we agree that if you had not placed anything in the conflict of interest disclosure, the journal
- 3 | and peer reviewers who reviewed your manuscript would
- 4 not know you were being paid by plaintiffs' counsel to
- 5 write the manuscript?

A. I review papers for GYN Oncology. I review papers for Reproductive Sciences. And I don't see

conflict of interest statements at all.

- 9 THE COURT: That wasn't his question. Let's 10 get to the bottom. This is why it is taking so long 11 today.
- All he asked is, if you did not include this

 conflict of interest statement, isn't it correct no

 one would have been aware you had consulted with a law

 firm involved in litigation on this topic. Isn't that

 correct?
- 17 THE WITNESS: Yes, your Honor.
- MR. LAPINSKI: What we are looking at is not the final disclosure that appeared in the manuscript.
- 20 MR. WILLIAMS: I'm getting to that. I'm
- 21 almost done.
- 22 BY MR. WILLIAMS:
- 23 Q. After being deposed in this case in January of
- 24 | 2019, you made additional revisions to your conflict
- 25 | disclosures. Right?

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This is stating that paying for the research. 1 Α.

- 2 Research, authorship and/or publication? Q.
- 3 Expenses of publication, yes. Α.
- Does it say expenses of publication? 4 Q.
- That's what I meant. 5 Α.
- You understand authorship refers to writing. Ιf 6 Q.
- 7 I'm an author of a book, I wrote the book. Can we
- 8 agree on that?
- 9 Α. Yes.
- You were the author of the manuscript; were you 10 Q.
- 11 not?
- 12 Yes. Α.
- 13 You were paid to author the manuscript.
- Correct? 14
- 15 For some part, yes. Α.
- 16 This funding disclosure says that the authors Q.
- received no financial support for the research, 17
- authorship and/or publication. Right? 18
- 19 Okay. Α.
- A person could come to the conclusion from 20
- reading that funding disclosure that whatever Dr. Saed 21
- 2.2 was paid for pursuant to the other disclosure, at
- least we know he wasn't paid to author or write this 23
- 24 manuscript. Right?
- 25 A. Possible.

```
229
            MR. WILLIAMS: No further questions, your
1
 2
    Honor.
 3
            THE COURT: You took less than 15. Thank you
    very much.
 4
            MR. LAPINSKI: Your Honor, can we have a short
 5
 6
    break, just five minutes?
 7
            THE COURT: All right.
8
            THE DEPUTY CLERK: All rise.
 9
            (Recess.)
10
11
    REDIRECT EXAMINATION
    BY MR. LAPINSKI:
12
13
    Q. Dr. Saed, we're going to go back to the binder
    that was plaintiffs' counsel's binder, and I want to
14
15
    look at your deposition on pages 30 through 32,
16
    please.
17
            Doctor, you were asked earlier in regard to
    your testimony at the top of page 32, the question
18
    was -- starting at the bottom of page 31, line 24, the
19
20
    question was.
21
            "QUESTION: As of the time you received the
22
    call from Ms. Thompson, what opinion did you have with
23
    regard to talc and ovarian cancer?"
            Do you remember being asked about that
24
25
    question and your response to that question?
```

Case 3:16-md-02738-FLW-LHG Document 11638 Filed 12/23/19 Page 230 of 276 PageID: Sae 043 Q direct/Mr. Lapinski

> 1 Α. Yes.

2 Before going to your answer, I would like to go Q.

230

3 to page 30 of your deposition. Starting at line 9,

you were asked the question as to whether there is a 4

causal link between talc and ovarian cancer. 5

And if you see on page 30, line 11, through 6

7 13, what was your answer to that?

8 A. I said:

"My opinion, anything that causes inflammation 9

and redox imbalance is linked to increased risk of 10

ovarian cancer." 11

12 O. Now, Doctor, with that in mind, when we go to

13 your answer on page 32, line 2, and your answer is

that "talc is a potential inducer of inflammation." 14

15 Correct?

16 Α. Yes.

17 After that you said it "induces and increases

the risk of ovarian cancer." Correct? 18

19 Α. Correct.

What did it refer to in that statement? 20 Ο.

21 Inflammation. Α.

22 Q. Doctor, you were asked questions about the

abstract that was submitted to SGO in March of 2019 23

and the fact that the submission to SGO made a 24

statement of testing for 48 hours. Correct? 25

- 1 A. Correct.
- 2 Q. I would like you to turn to your binder at the
- 3 back of the binder marked as PSC Saed Exhibit 3.
- Doctor, let me know when you have that in
- 5 front of you.
- 6 A. Say that again.
- 7 Q. The exhibit is marked PSC Saed 3.
- 8 MR. LAPINSKI: Your Honor, if you would like,
- 9 I can hand a copy up to you.
- 10 Q. Doctor, can you please describe for me what that
- 11 exhibit is.
- 12 | A. This is the abstract that we submitted to SGO
- 13 and it is presented by Dr. Harper. It induces a
- 14 | pro-oxidant state in normal and ovarian cancer cells
- 15 | through gene point mutations.
- 16 Q. Dr. Saed, is that the poster that you submitted
- 17 to SGO in March of 2019?
- 18 A. Yes.
- 19 Q. Is that the poster presented to SGO in March of
- 20 2019?
- 21 A. Yes.
- 22 | Q. What are the hours that are noted on that poster
- 23 | that was presented at SGO in 2019 as far as treatment
- 24 | hours?
- 25 A. 72 hours.

- 1 Q. Doctor, does your research conclude that
- 2 Johnson's Baby Powder causes oxidative stress and
- 3 ovarian cancer?
- 4 A. Yes.
- 5 | Q. Is it your opinion oxidative stress and
- 6 | inflammation leads to ovarian cancer?
- 7 A. Yes.
- 8 Q. Is it your opinion that Johnson's Baby Powder
- 9 | causes ovarian cancer?
- 10 A. Yes.
- 11 | Q. Doctor, what are those opinions based upon?
- 12 | A. It is based on all the results I established in
- 13 | my laboratory and my 25 plus years of experience
- 14 | characterizing the hallmark of ovarian cancer in
- 15 | relation to -- specifically, in relation to oxidative
- 16 stress and inflammation and also in published
- 17 literature.
- 18 Q. Doctor, there were some questions that were
- 19 asked, and I'm not sure the record was clear, so I
- 20 | want to go back and try to clarify it.
- You were asked some questions as to what was
- 22 | written first, the manuscript that you submitted to
- 23 | Gynecologic Oncology or the report you submitted in
- 24 | this litigation. Could you just clarify which was
- 25 written first, your manuscript or your expert report

in this litigation? 1

- 2 I believe the report first. Α.
- 3 The report first that you submitted in November? Q.

- I think November, and the manuscript was in --4 Α.
- 5 I'm not good on dates.
- 6 Doctor, take a look, if you would, at first the Q.
- 7 exhibit that's in your binder, which is your expert
- 8 report. What's the date of that expert report?
- November 2018. 9 Α.
- Doctor, do you recall when it was that you 10
- submitted the manuscript to Gynecologic Oncology? 11
- 12 August 2018. Α.
- 13 Doctor, does that refresh your recollection as
- 14 to which was written first, the manuscript or the
- 15 expert report?
- 16 Α. Yes.
- 17 Which was written first, the manuscript or the
- expert report? 18
- 19 The manuscript. Α.
- Doctor, going back to the testimony that we just 20
- went through in regard to cell proliferation. Is it a 21
- 22 generally accepted practice to leave a blank on a
- 23 plate?
- 24 Add a blank to a plate, planning experiment?
- 25 Yes. Q.

Sae 1043 Redirect/Mr. Lapinski

- Yes. 1 Α.
- 2 Doctor, if someone wanted to, could they Q.
- 3 replicate your studies based upon the description in

- your manuscript? 4
- 5 Yes. Α.
- Doctor, some of the research you did in regard 6 Q.
- 7 to Johnson & Johnson's Baby Powder dealt with CA-125.
- 8 Right?
- 9 Α. Yes.
- What is the relevance of CA-125 in your 10 Q.
- experiments? 11
- 12 CA-125 is a cancer antigen marker; and if it is
- increased, and it is increased when cells are exposed 13
- to Johnson & Johnson Baby Powder. That is very 14
- significant. It's a cancer antigen marker. 15
- The research you did regarding Johnson's Baby 16 Q.
- Powder was in vitro? 17
- 18 Α. Yes.
- Doctor, are doses in in vitro studies used to 19
- predict exposure in humans? 20
- 21 A. No.
- 2.2 Q. Why is that?
- 23 Because in concrete studies is a completely
- different environment; and also the cells you are 24
- 25 dealing with 100 percent of the same type of cells in

- 1 one concentration. In the human body it is all over.
- 2 | Q. Doctor, if you would in your binder, turn to
- 3 | Exhibit G in your binder. It is PSC Saed OP Exhibit
- 4 | G. And if you would, Doctor, if you could turn to
- 5 page 20.
- 6 Doctor, what is that on page 20 that we are
- 7 | looking at?
- 8 A. CA-125 --
- 9 Q. Take a look on the screen and make sure you are
- 10 | looking at the right page.
- 11 | A. Oh, this is the plan of the experiment that we
- 12 | did using Johnson & Johnson Baby Powder looking at
- 13 different doses -- 5, 50, 100 micrograms per
- 14 | milliliter for 72 hours; and these are the lists of
- 15 all cells that we used in the study, and they are each
- 16 | cell line treated, untreated with different doses
- 17 | giving an ID.
- 18 Q. Doctor, what's the significance of the ID number
- 19 | that's next to each cell line?
- 20 A. The ID is what is transported into the
- 21 | electronic data.
- 22 | Q. Doctor, if we were to go to your electronic data
- 23 and we were to look at your electronic data, would we
- 24 | be able to correlate each cell line based upon the ID
- 25 | number with the data that's in your chart?

Saed Redirect/Mr. Lapinski

- 1 A. Yes.
- 2 Q. Doctor, while there is a lot of cross-outs on
- 3 here, which makes us think white-out may be good
- 4 | sometimes, is it clear here, Doctor, you have your six
- 5 | different cell lines, and for your six different cell
- 6 lines you have the different amount of treatment?
- 7 A. Yes.
- 8 Q. If we could look at the top of that page,
- 9 Doctor, what's the treatment time associated with all
- 10 of those cell lines?
- 11 A. 72 hours.
- 12 | O. Doctor, when was it that that was treated?
- 13 What's the date on that page, Doctor?
- 14 | A. February 1st.
- 15 Q. Doctor, the experiments you did related to
- 16 | Johnson's Baby Powder, if we flip now to Exhibit H in
- 17 the binder.
- 18 First of all, Doctor, can you identify for me
- 19 | what Exhibit H in the binder is?
- 20 A. This is the description of the beginning of the
- 21 experiment using only Johnson & Johnson Baby Powder
- 22 | with the identification of the lot number and the cell
- 23 line.
- 24 Q. Doctor, if you would flip to the third page,
- 25 | which is page No. 32, that also has Bates No. Saed

- 1 000003. Doctor, what is that spreadsheet that's shown
- 2 on that page?
- 3 A. This is the spreadsheet with the sample ID which
- 4 | corresponds to the same ID you just showed which we
- 5 | treated with the different doses with Johnson &
- 6 Johnson Baby Powder for 72 hours.
- 7 Q. Doctor, were all of the samples that you used in
- 8 | the Johnson's Baby Powder study those samples
- 9 identified there treated for 72 hours?
- 10 A. Yes.
- 11 | Q. Doctor, you were able to confirm that in your
- 12 | lab notebook?
- 13 A. Yes.
- 14 Q. Doctor, in order for you to reach the
- 15 | conclusions that you reached and you are expressing in
- 16 your expert report, was it necessary to compare the
- 17 dose that you used in in vitro studies with an amount
- 18 | equivalent to human exposure?
- 19 A. No.
- 20 Q. Why is that?
- 21 A. In vivo human studies are completely different.
- 22 | It needs a different setup.
- 23 | Q. Doctor, do you need animal studies to support
- 24 | the opinions you are offering in this case?
- 25 A. No.

- 1 Q. Doctor, the final manuscript that you published
- 2 | in Reproductive Sciences in February of 2019, did that
- 3 | final manuscript correctly reflect the fact that the
- 4 Johnson's Baby Powder, that the cell lines that were
- 5 | treated with Johnson's Baby Powder were treated for
- 6 72 hours?
- 7 A. Yes.
- 8 Q. Dr. Saed, you were asked several questions in
- 9 regard to white-out that was in your laboratory
- 10 notebook. Do you recall that?
- 11 A. Yes.
- 12 | Q. Dr. Saed, the questions that were asked about
- 13 | the white-out were questions for the most part in
- 14 | regard to the section of your notebook that has been
- 15 marked as PSC Saed OP Exhibit I. Correct?
- 16 A. Yes.
- 17 Q. Dr. Saed, in addition there were some white-outs
- 18 | in the section that was marked as PSC Saed OP Exhibit
- 19 G. Correct?
- 20 A. Yes.
- 21 Q. Were those sections of the laboratory notebook
- 22 | performed before you started doing your testing on
- 23 Johnson's Baby Powder?
- 24 A. One more time, please.
- 25 Q. Sure. Exhibit I and Exhibit G, which are copies

- 1 of the first two sections of your laboratory notebook,
- 2 do those two sections of the laboratory notebook
- 3 pertain to work that you did on talcum powder before
- 4 | you started your experiments on Johnson's Baby Powder
- 5 | that form the substance of the manuscript that you
- 6 published?
- 7 A. Yes.
- 8 Q. Dr. Saed, there was note made of the fact that
- 9 on one of the pages of your laboratory notebook in
- 10 Exhibit H, specifically, page 53 of that notebook,
- 11 | which is Bates stamp number Saed 000025, that there
- 12 | was white-out and Johnson & Johnson was written on top
- 13 of the white-out. Do you recall that?
- 14 A. Yes.
- 15 | Q. Dr. Saed, how were you able to confirm Johnson's
- 16 Baby Powder was in fact used for all of your
- 17 experiments that start in Exhibit H?
- 18 A. This Exhibit H is everything we used in this
- 19 exhibit where we published the manuscript. It is all
- 20 | done with Johnson & Johnson Baby Powder.
- 21 Q. How are you able to confirm that, Doctor? Flip
- 22 | to the first page of Exhibit H, if that will assist
- 23 you.
- 24 A. If you go to the first page, your Honor will see
- 25 | that. Everything in this section is done with this

```
240
    powder.
1
 2
          Doctor, you were asked questions about work that
    Q.
 3
    you performed that was later added to your laboratory
    notebook. Do you recall those questions?
 4
          Yes.
 5
    Α.
 6
          Doctor, any of the data that was run related to
    Q.
 7
    your experiments on Johnson's Baby Powder, was the
8
    data run prior to your writing and submitting your
 9
    manuscripts for consideration to Gynecologic Oncology?
          Before we submit, of course.
10
          Was all of the data related to Johnson's Baby
11
    Q.
12
    Powder and the results that you found and submitted as
13
    a manuscript to Reproductive Sciences run and analyzed
14
    before you submitted the manuscript?
15
    Α.
          Yes.
16
            MR. LAPINSKI: I have no further questions.
17
            MR. WILLIAMS: No questions, your Honor.
            THE COURT: Thank you. You are excused,
18
19
    Doctor.
20
             (Witness excused.)
21
            THE COURT: Okay. 9:30 tomorrow morning.
2.2
            THE DEPUTY CLERK: All rise.
23
            (Court adjourned at 6:10 p.m.)
    ///
24
25
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CERTIFICATE PURSUANT TO TITLE 28, U.S.C., SECTION 753, THE FOLLOWING TRANSCRIPT IS CERTIFIED TO BE AN ACCURATE TRANSCRIPTION OF MY STENOGRAPHIC NOTES IN THE ABOVE-ENTITLED MATTER. S/Vincent Russoniello Vincent Russoniello, CCR Certificate No. 675

•
Q.
w

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